REINVENTING THE FEDERAL FOOD SAFETY SYSTEM

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

AND

JOINT HEARING

BEFORE THE

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

AND THE

INFORMATION, JUSTICE, TRANSPORTATION, AND AGRICULTURE SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST AND SECOND SESSIONS

NOVEMBER 4 AND 19, 1993; MAY 25; AND SEPTEMBER 28, 1994, HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

JUNE 16, 1994, JOINT HEARING

VOLUME 1

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REINVENTING THE FEDERAL FOOD SAFETY SYSTEM
(USDA's Progress in Reforming Meat and Poultry Inspection)

THURSDAY, NOVEMBER 4, 1993

HOUSE OF REPRESENTATIVES,
HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 2247, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the subcommittee) presiding.

Present: Representatives Edolphus Towns, Donald M. Payne, Steven Schiff, John L. Mica, and Rob Portman.

Also present: William M. Layden, professional staff member; Martine M. DiCroce, clerk; and Martha B. Morgan, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN TOWNS

Mr. TOWNS. The Committee on Government Operations' Human Resources and Intergovernmental Relations Subcommittee will come to order.

This is the first of a series of hearings on reinventing the Federal food safety system. Today we will review USDA's progress in reforming meat and poultry inspection.

The Federal Government spends $1 billion each year on food safety activities. But what are taxpayers getting annually for their money; 9,000 deaths; 80 million people sick, some chronically disabled; $8 to $17 billion in medical costs each year from food tainted with deadly microbes such as E. coli 0157:H7.

If we are truly going to reform health care, we must start with the basics: Prevention. We must prevent foodborne disease, not just treat its victims.

The Vice President's report on reinventing government is alarming. It concluded that the Federal Government's multiple agencies responsible for ensuring the safety of the Nation's food supply are not progressing fast enough in understanding and overcoming life-threatening illness. In fact, the report states that the multiple agencies are not adequately protecting Americans.

The current Federal food safety system is not just fragmented; it is broken. The system is not designed to prevent foodborne disease. The system is not designed to prevent the 4 deaths and 500 ill-

nesses caused by E. coli 0157:H7 earlier this year; and yet this outbreak could have been prevented. There is no question about it. USDA has known for over 20 years that its inspection system cannot detect harmful microbes in meat and poultry, but did absolutely nothing about it.

Earlier this year, Agriculture Secretary Mike Espy announced 33 initiatives to reform meat and poultry inspection. Let me say, I applaud the Secretary for his initiatives. But given USDA's past track record, I want to be sure that we are progressing fast enough to protect Americans.

At this moment, I cannot say that we are.

Today, we will hear about the progress USDA is making to reform the safety of meat and poultry. On November 19, we will hold USDA accountable.

On a later date, we will evaluate the progress FDA is making to ensure the safety of seafood and other food products.

Historically, as a country we have revised Federal food safety responsibilities only in response to a crisis or calamity. But I ask: Must we wait for the next tragedy if we can prevent it?

Over the years there have been numerous recommendations to restructure Federal food safety efforts.

I ask unanimous consent to include in the record a Congressional Research Service report requested by the subcommittee that summarizes these previous recommendations.

[The information can be found in appendix 2.]

Mr. TOWNS. At this time, I would like to yield to Congressman Schiff from Albuquerque, NM, for any remarks he has to make.

Mr. SCHIFF. Mr. Chairman, I will be very brief. We have a number of witnesses waiting to testify, including our colleague.

I must say that I congratulate you and commend you for holding this hearing. The information the subcommittee staff has put together is nothing short of alarming. The statements of witnesses reinforce that. I look forward to hearing the witnesses personally.

I want to add, I understand the Department of Agriculture will be invited to a later hearing to testify on this issue and respond. I only hope that they choose to send, if not the Secretary himself, who I think in this particular case, in view of the information, would be warranted, the highest possible policy official at the Department of Agriculture who can respond on the situation we are reviewing today. I think the situation more than merits that response from the Department of Agriculture.

I yield back, Mr. Chairman.

Thank you.

Mr. TOWNS. Thank you very much, Congressman Schiff.

I agree with you. I think we need to have a high-level person to answer some of the questions we are raising.

Before we begin, I would like to say to all of our witnesses that the full text of your statement will be included in the record. I would like to ask each of you to summarize your testimony in approximately 5 minutes so we will have time to ask questions.

We will have a light here which starts out green; when your 5 minutes is up, in case you get carried away, it turns red. When it turns red, that means your 5 minutes are up. We hope you will re-

spect the time limit so that the Members will have an opportunity to ask questions.

We are delighted this morning to have with us one of our colleagues, Congressman Kreidler from Washington State who has been very involved in this issue before coming to the U.S. Congress.

You may proceed at this point any way you wish. We look forward to working with you further on this important issue.

STATEMENT OF HON. MIKE KREIDLER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. KREIDLER. Mr. Chairman, I want to commend you for holding this important hearing. We do need to pay much closer attention to our food safety system, a system that you so ably pointed out has very serious flaws. Congress especially needs to reform the inspection system for meat and poultry which we can no longer rely on to protect public health.

Back in 1907 Congress promised the American people it was going to protect food safety. That is a promise that has been broken, not because of bad intentions or even because of the inadequate funding, but because the inspection system has failed to keep up with scientific knowledge. As a result, our children are paying the ultimate price for this failure.

Three children in my State died last winter because they were poisoned by hamburgers that the government had labeled as wholesome. More than 40 other children were hospitalized and more than 500 people were affected by this single outbreak of E. coli. This is the largest incident of E. coli infection in recent years, but smaller outbreaks are happening all the time all over the country.

Food safety is everybody's responsibility; but our government must take the lead in this system of ours.

As you pointed out, Mr. Chairman, we spend hundreds of billions of dollars on our meat inspection system today in this country; and we certainly deserve as Americans to have a system that works.

Last spring, I introduced H.R. 1786, a bill to modernize the meat and poultry inspection system, that calls for improvements in the inspection system, microbial testing of meat and poultry samples, more research on pathogens, and labels for cooking and handling instructions.

I regret, Mr. Chairman, that the House Committee on Agriculture has taken no action on this proposal or any others. The Department of Agriculture is scarcely doing any better.

Last winter, Secretary Espy promised reforms in the inspection system; but the Department has stumbled and fumbled through this year, with little progress to show for it.

Mr. Chairman, you are going to hear more from other witnesses about these problems.

Mr. Chairman, USDA still doesn't get it. It still is trying to modernize an inspection system without upsetting the meat industry. How many more children are going to have to suffer and die as a result of the Department not putting American families first?

Vice President Gore, as you pointed out, has presented to the Congress the National Performance Review recommendations. One of those is to shift food inspection to the Food and Drug Adminis-

tration. Frankly, getting the job done is more important to all of us than who does the job.

After watching the USDA stumble and fumble since January 1, I am ready to support that shift to the FDA.

You are doing the public a great service by holding this hearing and hopefully being able to move on these recommendations.

You will hear more about these issues from Washington State witnesses who, unfortunately, have had very sad firsthand experience.

I want to work with you, Mr. Chairman, so that we see real change in the way we do food, meat, and poultry inspections in this country. I want to particularly thank you, Mr. Chairman, for allowing me to come and say a few words about the need to address this issue.

[The prepared statement of Mr. Kreidler follows:]

STATEMENT OF CONGRESSMAN MIKE KREIDLER
SUBCOMMITTEE ON HUMAN RESOURCES & INTERGOVERNMENTAL OPERATIONS
COMMITTEE ON GOVERNMENT OPERATIONS
Hearing on USDA Meat and Poultry Inspections
November 4, 1993

Mr. Chairman, I want to commend you for holding this hearing. Congress needs to pay much closer attention to our food safety system -- a system with serious flaws. And Congress especially needs to reform the inspection system for meat and poultry, which we can no longer rely on to protect the public's health.

In 1907, Congress promised the American people that government would do its best to assure food safety.

That promise has been broken -- not because of bad intentions, or even because of inadequate funding, but because the inspection system has failed to keep up with scientific knowledge. As a result, our children are paying the ultimate price for that failure.

Three young children in my state died last winter from poisoned hamburger their government had labeled "wholesome." More than 40 other children were hospitalized. In all, more than 500 people were affected from this single outbreak of E. coli 0157:H7.

That was the largest incident of E. coli infection in recent years, but smaller outbreaks happen all the time, all over this country. Right now two children from Bellingham, Washington are in a Seattle hospital with E. coli infection; one is undergoing dialysis. Last month there was a cluster of nine cases in eastern Washington State and northern Idaho. Now that most states are moving to require doctors to report this type of E. coli infection, we will no doubt hear about other outbreaks more often.

Food safety is everybody's responsibility, but our government must take the lead in instituting a responsible inspection system. Americans who spend over $500 million a year on meat and poultry inspection deserve a system that works better than the one we have now.

Last spring, I introduced H.R. 1786, a bill to modernize meat and poultry inspection. It called for improvements in the inspection system, microbial testing of meat and poultry samples, more research on pathogens, and labels with cooking and handling instructions. I regret that the House Committee on Agriculture has taken no action on this proposal or anything like it.

The Department of Agriculture is scarcely doing better. Last winter, Secretary Mike Espy promised reforms in the inspection system. But the Department has stumbled and fumbled through this year with little progress to show for it:

-- It delayed a labeling requirement until this summer, and then used an "emergency" rule-making procedure that has been rejected in court. Only this week has the Department begun the orderly rule-making process it should have started last spring -- if not 20 years ago, when the first lawsuit was brought to require safe handling and cooking labels.

-- The Secretary's "zero tolerance" policy on fecal contamination of meat has been applied vaguely and inconsistently. Written instructions to inspectors were delayed for months. Now there are reports that the Department intends to rely on the industry, rather than its own inspectors, to detect and report fecal contamination.

-- Testing meat samples for bacterial contamination is essential to measure whether the inspection system is doing any good. The National Academy of Sciences recommended the development of such tests in 1985. Last May, the Secretary directed the Food Safety and Inspection Service to publish, within 60 days, criteria for rapid tests for bacterial contamination. No criteria were published until two weeks ago.

Mr. Chairman, USDA still doesn't get it. It is still trying to modernize the inspection system without upsetting the meat industry. How many more children must suffer and die before the Department starts putting American families first?

Vice-President Gore's National Performance Review has recommended shifting the inspection system to the Food and Drug Administration. Frankly, getting the job done right is more important than who does the job. But after watching USDA stumble and fumble since January, I am ready to support that shift to FDA.

You are doing a great public service by having this hearing, Mr. Chairman. You will hear more about these issues from some Washington State witnesses who, unfortunately, have had first-hand experience. I want to work with you for real change in the way we assure the safety of meat, poultry, and other foods. Thank you again for this chance to be here.

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Mr. TOWNS. Thank you very much, Congressman.

We look forward to working with you. I also would like to thank you for the work that you are doing in terms of highlighting this issue in your bill that you put forth. Let's hope as a result of what we are doing, we can get the kind of activity that is needed to be able to protect people. This is what we are talking about.

We are hoping that as a result of our hearings, we can find out what USDA has done. In the event nothing is happening, I might even join you in supporting the transfer of meat and poultry inspection from USDA to FDA. The point is, let's first find out what is happening.

I would like to yield to Congressman Schiff, the ranking member.

Mr. SCHIFF. I have a matter I want to ask our colleague about.

I want to thank you for your leadership in this issue and your testimony today.

I think we all recall the tragic events in the State of Washington that are partly responsible for the hearing we are having today. I have a question about that incident. I ask this question with no intent to point a finger at anyone or not to point a finger if someone is responsible.

For aid to us in this oversight hearing, from the accounts that occurred following those incidents, it was never clear to me from the media whether the source of the infection was—should be—was the meat supplied to this fast-food restaurant or some deficiency in cooking, because I think it can be accepted that even with the best preventive measures, meat that has been properly prepared, in most cases, ought to be cooked.

I wonder if you determined in the work you have already done, in this particular instance, what caused the tragedy we all saw in your State?

Mr. KREIDLER. First, there certainly was contaminated meat. Second, inadequate cooking of that meat took place.

Part of it is the inspection system itself, being able to identify through the process of meat production, from the slaughterhouse to where the meat then is wholesaled and stored, cold storage, and so forth, and finally ends up at the end user, and it is improving that system. It was contaminated meat.

The second part was the adequacy of the cooking of the meat that took place in the restaurant itself, in this case, a Jack-in-the-Box Restaurant. There were higher cooking standards required by the State of Washington that were not being followed by the restaurant; so they were not following the rules.

There was a reporting requirement in the State of Washington, which is among several States that require that they report E. coli. That is not true universally. I think the State was on top of it in making an early identification of E. coli.

He was able then to be able to make the identification. Of course, the nature of the fast-food restaurants, in the uniformity in which they cooked meat in their process, meant that once they had contaminated meat in the system, it was more likely you would have multiple outbreaks; unlike other situations where you might have a restaurant where maybe a few patties were not cooked right. But if they were cooked completely, they would have killed the patho-

gens and it was unlikely you would have had that uniformity of cooking that would have happened in a fast-food operation.

It was unique in getting it into the stream of things with a fast-food restaurant—then it was more likely to have resulted in a major outbreak as opposed to what has happened frequently and not been identified, where you would have outbreaks here, but it may have been a very limited number of individuals. And frequently, even physicians are not going to recognize it for what it is, because until recently, with the publicity, there wasn't information being put out as to the signs and symptoms of this particular type of pathogen.

Mr. SCHIFF. If I understand your response then, everything happened in this situation? The contaminated meat getting into the system, to undercooking, beneath the standards the State of Washington sets for consumer health?

Mr. KREIDLER. Exactly.

Mr. SCHIFF. Is that correct?

Mr. KREIDLER. That is correct. The one good thing is there is a requirement in the State for reporting, which was a good thing to see happen because that allowed you to identify that you did have a particular pathogen that was causing an epidemic here, in effect, because of its presence in the meat supply system, you could step in and, hopefully, make corrective actions as quickly as possible.

Mr. SCHIFF. Thank you very much.

I yield back, Mr. Chairman.

Mr. TOWNS. Thank you very much.

Let me thank you again for your testimony. As I said earlier, we look forward to working very closely with you.

Let me say to you, I do understand your frustration. There is no question about it. There is a lot of frustration on this side as well.

Thank you again. We look forward to working with you.

Mr. KREIDLER. Thank you, Mr. Chairman.

Mr. TOWNS. At this time, we will call our first panel: Suzanne Kiner from Washington State; Janis Sowerby from Michigan; Mary Heersink from Alabama; Dr. Edgar Marcuse from the Children's Hospital and Medical Center in Seattle, WA; and Dr. Paul Blake from the Centers for Disease Control and Prevention.

It is customary that all witnesses who appear before this committee are sworn.

If you will stand?

[Witnesses sworn.]

Mr. TOWNS. Let the record show the witnesses have answered in the affirmative.

Thank you very much.

Let me also say again that your entire statement will be included in the record, every period, every question mark, every "T," every "I" will be included.

If you will just be kind enough to summarize and at the end of the 5 minutes, we will be able to raise questions with you.

Let me say again, we thank you so much for coming.

Ms. Kiner.

STATEMENT OF SUZANNE KINER, PARENT OF AN E. COLI 0157:H7 VICTIM

Ms. KINER. My daughter, Brianne Kiner laid in a hospital bed for 167 days. For 55 of those days she was dying.

Our story begins with a tainted hamburger that Brianne ate in early January. Along with a 103.8 degree fever, she had abdominal cramps every 10 to 12 minutes. She would turn pale and not say a word. A frantic visit to our pediatrician's office at 10 p.m. was not reassuring. After taking a urine sample—I thought it was a urine sample—I came up with a cupful of blood that poured over the cup's edge, over my hand and it was coming out of Brianne's intestines.

This petite, dark-eyed girl with brown hair, long and flowing to her waist like liquid silk, was beginning her journey. This journey came with its own hell. Brianne's pain right from the beginning was horrific. There is no courage—a medical term—for her agony. Brianne slept for 20 minutes in the first 80 hours of hospitalization only after being given a drug named fentynl; this drug is 100 times stronger than morphine.

The most frightening change in Brianne was her mental status. In the space of a few short hours, she plummeted from a bright 10-year-old to a frightened 2-year-old. This was not an emotional regression. Brianne's brain was already beginning to swell. Her voice pitch climbed and her vocabulary became simpler.

My daughters's mind was slipping away; there was nothing I could do to stop it. The ravages of the coma were only just beginning. I was grateful when she slipped into a full coma. At least she wouldn't suffer as painfully then.

My daughter's last spoken words to me were: Mommy, take me home, I don't mess my bed there.

The ventilator came next, and unbelievably, I was grateful for it. Brianne's breath was up to 100 breaths per minute in this horrible race. At this point 13 machines fought for her, a machine to breathe for her, machines to monitor her heart; her blood pressure was falling to 40 over 20. She laid there for days. She laid there with one foot in this world and the other in the next.

Brianne coded. CPR was performed. Her heart was barely functioning. We were asked to plan our daughter's funeral and allow an autopsy.

It wasn't as if she would die, it was when would be her last breath.

Have you ever planned a child's funeral?

I knew classmates would come. This would be their first exposure to the grim realities of what disease can do to someone their own age. Brianne's school brought in counselors. These kids were scared to death that they could die from the E. coli also. Part of the horror for me as a parent and an adult is I cannot promise them or anyone else that they will not be touched by this poison that flourishes currently in our system.

Brianne's body continued to be ravaged by toxin. Organ by organ, her tender petite body was in failure. Her heart was a piece of "mush." It was bleeding from every pore. Her blood vessels had no boundaries. The fluid that makes up 80 percent of her blood was continuously flowing out into her tissues. Crystals formed inside

her arteries that cut the red blood cells. The toxins shut down Brie's liver, kidneys, lungs, pancreas. Insulin was added.

Brianne by now had three open gut surgeries. They couldn't even close the wound because she was so swollen. Her brain went into grand mal seizures. By now I was being told her brain damage was so severe she would be a vegetable for rest were her life.

My daughter had thousands of seizures. Then came the news that she was essentially brain dead and had half of a dead brain stem. The recommendation was to pull the plug.

Ladies and gentleman, we had a miracle from God. But this does not change what Brie went through nor diminish the damage to her body now. My daughter lives with an uncertain future. I cannot promise her or any other child that they will not get this horrific disease.

This is not the situation that these cases are just now coming to light.

Our children are not expendable. They are not to be a statistical death rate that is acceptable to the meat industry. I am here to prevent your child or your grandchild from dying from the most painful death conceivable.

Thank you.

Mr. TOWNS. Thank you very much.

[The prepared statement of Ms. Kiner follows:]

TESTIMONY OF SUZANNE KINER

My daughter, Brianne Kiner laid in a hospital bed for 167 days. For fifty-five of those days she was dying.

Our story begins with a tainted hamburger that Brianne ate in early January. Within a few days Brie had a fever that was rising with alarming speed. Along with 103.8 she had abdominal cramps every ten to twelve minutes. She would turn pale and not say a word. The beginning of Brianne's courage. A frantic visit to our pediatrician's office at ten o'clock that night did not bring comfort. The next indication of how serious Brianne's illness was within fifteen minutes. She asked to go to the bathroom. I knew the pediatrician would want a urine sample. When I brought the sterile cup up from beneath her, the cup was filled with blood and her blood was running over my hand. Brianne asked "What is that mommy?" I told my nine year old daughter it was the raspberry Popsicle she had slowly sucked on six hours earlier. That was the only food or liquid Brianne would take by mouth for the next three months. I then carried Brianne to her exam room, laid her down, and went and set the specimen down in front of Dr. Mauseth. Immediately he suspected it was E coli 0157:H7. Because Brianne was dehydrating, she was administered an IV fluid. She laid her arm out without complaint for the first of many invasive procedures. This petite, brown eyed, with long matching dark brown hair that flowed like liquid silk almost to her waist was beginning her journey.

This journey came with its own hell. Brianne's pain right from the beginning was horrific. There was no courage (a medical term) for her agony. Brie slept for twenty minutes in her first eighty hours of hospitalization only after being given a drug named fentynl. This drug is one hundred times stronger than morphine. Even with three progressive dosage levels that her anesthesiologist administered to Brianne with tears in his eyes, this child, my daughter, only slept for those brief moments. Then the cramping and gushing of blood from her intestines wrenched Brianne to an awakened horror again.

The most frightening change in Brianne was her mental status -- in the space of a few short hours she plummeted from a bright ten year old to a frightened two year old. This was not emotional regression. Brianne's brain was already beginning to swell. Her voice pitch climbed and her vocabulary became simpler. My daughter's mind was slipping away. And there was nothing I could do to stop this horror.

The ravages of the coma were only just beginning. I was grateful when she slipped into a full coma -- at least she wouldn't suffer as painfully then. My daughter's last spoken words to me were "Mommy, take me home, I don't mess my bed at home." The ventilator came next and unbelievably I was grateful for it. Brianne's breathing was up to 100 breaths per minute in this horrible race for life. When she was finally on

the ventilator it meant her body wouldn't have to burn calories she wasn't getting. Her weight dropped from 64 lbs. to 42 lbs. Thirteen machines at this point fought for her; a machine to breathe for her, machines to monitor her heart, her blood pressure was falling to 40/20. She lay there with one foot in this world and the other in the next. Brianne coded. CPR was performed. They used heart medicines in combinations never tried before. Her heart was barely functioning. We were asked to plan our daughter's funeral and allow an autopsy.

It wasn't if she would die, it was when would be her last breath. Have you ever planned a child's funeral? I knew classmates would come, this would be their first exposure to the grim realities of what disease can do to someone their own age. Brianne's school brought in counselors. The kids were scared to death that they too could die from E. coli 0157:H. Part of the horror for me as a parent and an adult is I cannot promise them or anyone else that they will not be touched by this poison that flourishes in our current system.

Brianne's body continued to be ravaged by the toxin. Organ by organ her tender petite body was in failure. Brianne had a brain swell, which could not be treated because it would without question finish off her heart that was already infected with endocarditis. Her heart was a piece of "mush," it was bleeding from every pore in her body. Her blood vessels no longer had any boundaries. The fluid that makes up eighty percent of our blood was continuously flowing out into her tissues. Crystals formed inside her arteries that cut the red blood cells. The toxins shut down Brie's liver, kidneys, lungs, pancreas. Insulin was added. I remember one doctor saying that kids with two system failures do not make it out of intensive care. I remember telling him this child would. Brianne, by now, had had three open gut surgeries. They couldn't even close the wound because she was so swollen. Her brain went into gran mal seizures. By now I was being told her brain damage was so severe she would be a vegetable for the rest of her life. My daughter had thousands of seizures. Then came the news that she was essentially brain dead and had half of a dead brain stem. The recommendation was to pull the plug. Ladies and gentlemen we had a miracle from God. But this does not change what Brie went through nor diminish the damage to her body now. My daughter lives with an uncertain future. I cannot promise her or any other child that they will not get this horrific disease. This is not the situation that these cases are just now coming to light. Our children are not expendable. They are not to be a statistical death rate that is acceptable to the meat industry. I am here to prevent your child or grandchild from dying from the most painful death conceivable.

Thank you for your time.

Mr. TOWNS. Ms. Sowerby.

STATEMENT OF JANIS SOWERBY, PARENT OF AN E. COLI 0157:H7 VICTIM

Ms. SOWERBY. Hello. I am Janis Sowerby. I am from Saranac, MI. My 3-year-old son Scott, passed away 3 months ago from hemolytic uremic syndrome, 9 days after eating a "sloppy joe" contaminated with E. coli 0157:H7. His illness started with painful stomach cramps, vomiting, and diarrhea, which turned bloody. He was taken to the doctor who immediately sent him to the hospital.

The first few days he wasn't given anything for pain because they didn't want to mask his symptoms. I stayed at the hospital in Scott's room afraid to leave his side. I spent hours stroking his little forehead and hugging him and listened to his tiny little voice crying: "Owee Mommy, owee."

The 4th day of Scott's stay at the hospital his kidneys started to fail. The results from his stool sample were confirmed for E coli. Scott was transferred to a larger hospital where there was a special pediatric intensive care unit. While we were waiting for the ambulance to arrive, Scott tried to speak to me but it was hard to understand him because his teeth were clenched together so hard he couldn't open his mouth. His last words to me were: "Mommy, will you please hug me."

Doctors at the other hospital told us Scott had hemolytic uremic syndrome. He was so pale he had no color in his lips. He was given blood transfusions and started on dialysis. Each day new problems would arise. His stomach became very swollen. He became diabetic and was injected with insulin. He began having seizures and was put on an artificial respirator.

Scott was taken in for CAT scans which revealed his brain was beginning to deteriorate. His thalamus, the part of the brain that controls all body functions was permanently damaged. He had to be put on medication to control his seizures, heart rate, breathing, and temperature.

On the evening of the 7th day, I stood by Scott's bed talking to him. As I spoke, his head turned toward me as if he could hear what I was saying. I was elated. I left the hospital that night totally exhausted and thinking things would be OK. I was wrong.

I received a phone call early the next morning and was told Scott was having more seizures and was being taken in for another CAT scan. When I arrived at the hospital, I was told the results revealed no brain activity at all. Only the machines were keeping his precious little body alive.

I will never forget the doctor telling me it was time to make the decision to take away the life support and let him die with some dignity. I screamed, "No, I cannot do this now. Not yet. I need time to think."

I prayed that he would come back to us. I asked to hold him in my arms. His little body was so heavy and so tangled with all the tubes. As I held him, I lifted up his eyelid and I knew he was no longer with us.

My son would not be coming home with me where he belonged. Finally, I told the doctor I was ready. We left the room so they

could shut off the equipment and remove all the tubes. Then I went in and held him one last time.

The next few minutes I spent crying and watching my son turn blue.

I want to address the issue of meat labeling because had I known then what I know now, Scott might be alive today. First of all, the labeling comes only as a settlement of a lawsuit filed by Beyond Beef. It does not come out of the goodness of the FSIS hearts.

Why did the USDA wait until August 1993 to attempt to implement labeling requirements for meat and poultry when according to nationwide studies in 1985, and 1990, they were convinced of the need for more direct methods of placing food safety information in the hands of consumers?

Why did the USDA not follow proper procedures for rulemaking? In reading a copy of the injunction from Texas filed by various food industry associations when the judge ruled against the labeling, the USDA did not rebut the plaintiffs showing an emergency does not exist to require an emergency rule. Does the USDA truly believe that this is not an emergency?

USDA's current labeling proposal is virtually meaningless. Nowhere does it state that the meat may contain bacteria that could lead to death. In a transcript in a session with Secretary of Agriculture Espy, Assistant Secretary of Marketing and Inspection, Eugene Brandstool, and Bob Sherwin whose child was a victim in the Jack-in-the-Box poisoning, Mr. Sherwin told the Secretaries "Some consumer groups would like to tell the people this may contain pathogens." Secretary Espy's reply was "We would not want to have a chilling effect on meat sales with anything like that. This is not a product like cigarettes, but I think we have to tell the public about proper handling without suggesting that definite harm might result."

I agree with the Secretary. This is not a product like cigarettes. Smoking takes a long period of some time to cause permanent damage to a persons health whereas contaminated meat killed my son in 9 days.

Thank you.

Mr. TOWNS. Thank you for your testimony.

[The prepared statement of Ms. Sowerby follows:]

STATEMENT OF JANIS SOWERBY
BEFORE THE HOUSE SUBCOMMITTEE ON HUMAN RESOURCES
AND INTERGOVERNMENTAL RELATIONS
GOVERNMENTAL OPERATIONS COMMITTEE
WASHINGTON, D.C.
NOVEMBER 4, 1993

My name is Janis Sowerby. I am from Saranac, Michigan. My 3 year old son Scott Hinkley passed away July 30th, 1993 from Hemolytic Uremic Syndrome (HUS) 9 days after eating a sloppy joe made from ground beef contaminated with E. coli 0157:H7. His illness began with painful stomach cramps, vomiting and diarrhea. Soon though his diarrhea became bloody. We took him to the doctor's office where he was immediately referred to the hospital. His final days in the hospital were the most horrible of my life. I could only stand by and watch while my son's precious little body was destroyed inch by inch.

At first, the doctors thought Scott had an intestinal blockage, so he was given a barium enema which eased his pain for a while. The next day, the pain and diarrhea reoccurred so he was given another enema. This time the enema didn't help. The doctors started to suspect other causes. Salmonella and various other organisms were ruled out after a stool sample was taken. The doctors began to suspect **E.coli** because of the symptoms Scott was experiencing.

Scott could not eat or drink because it aggravated his pain.

The first days in the hospital the doctors would not prescribe any pain medication for him because they were afraid medication would mask the symptoms. I stayed by Scott's bedside afraid to leave him alone. I spent hours stroking his little forehead and hugging him as I listened to his tiny little voice cry "owie Mommie, owie." His pain was so severe he could not sleep for days on end.

The first 2 days Scott was in the hospital when he had to urinate he was able to stand at the toilet, but by the third day his pain was so severe he could no longer stand. He was just potty trained and so proud that he was a big boy. Every time he experienced the wrenching pain from his diarrhea he would cry and ask "Mommy, can I poop my pants?" By this time the doctors started Scott on morphine to alleviate some of the pain and allow Scott to get some rest.

On the fourth day of Scott's stay at the hospital his kidney's started to fail. The pediatrician came and told me the results from the stool culture were confirmed for E.coli 0157:H7. I was very terrified having no idea what affect this organism could have on my son's body. The doctor recommended that Scott be transferred by ambulance to a larger hospital where there was a special pediatric unit and around the clock medical care.

While we were waiting for the ambulance to arrive, Scott tried to speak to me. It was very hard to understand him because his teeth were clenched together so hard he couldn't open his mouth. I kept asking him to repeat himself and finally I heard him say "Mommie, will you please hug me?" Those were the last words my son

spoke to me. I will never forget the terror in his eyes as we were riding in the ambulance to the other hospital. I held back my tears knowing if I cried it would only frighten him more.

When we arrived at the next hospital, those doctors told us Scott had Hemolytic Uremic Syndrome (HUS). I had never heard of this disease. I asked them if they would get me a reference book so I read about HUS. Not much information was available but there was enough to tell me that this was an extremely serious condition.

By then Scott was so pale that he had no color in his lips. I was told that Scott needed to have blood transfusions and be put on kidney dialysis. He was given a sedative. Then we were asked to leave the room so the doctors could insert tubes down his nose and I.V. lines through both shoulders and his groin area. Little did we know that this would be the last time we would ever see Scott conscious.

I kept telling myself that he would be all right. He had to be. But each day new problems would arise. His stomach became very swollen. He became diabetic and had to be injected with insulin. He began having seizures. He was put on an artificial respirator. Scott was taken in for CAT Scans which revealed that his brain was beginning to be affected. His thalamus, the part of the brain that controls all body functions, was now permanently damaged. He had to be put on medication to control his seizures, heart rate, breathing and temperature. He was placed on heating blankets but still his body was extremely cold.

On the evening of the seventh day I stood by Scott's bed. As

I spoke his head turned towards me as if he could hear me. I was elated. I thought for sure he would come out of his coma and be all right. I left the hospital that night totally exhausted but thinking things would be ok. I was wrong. I received a phone call early the next morning informing me that Scott was having more seizures so they were taking him in for another CAT Scan. When I arrived at the hospital the doctors told me this time the results revealed no brain activity AT ALL -- only the machines were keeping his tender little body alive.

I will never forget the doctor telling me it was time to make a decision to take the life support away and let him die with some dignity. I was in total shock. I screamed, "No I can't do this now! Not yet. I need time to think." Hours went by. I prayed that he would come back to us. I asked to hold him in my arms. His little body was so heavy and so tangled with all the tubes. As I held him, I lifted up his eyelid and I knew that he was no longer with us. My son would never come home where he belonged. My mother, Scott's stepfather and all my friends wanted a chance to hold him one last time before we shut off the life support.

Finally, I told the doctor we were ready. We left the room so they could shut off the equipment and remove the tubes. Then I went back in and held him one last time. The next few minutes I spent crying and watching his little body turn blue. We had been defeated.

I miss my son. Not a day goes by without tears shed for my precious boy. My eleven year old daughter has a hard time even

talking about her only sibling. She is very angry and in great denial about his death. She seems to believe that he is sleeping although she knows he can't come home where he belongs. We have had to send her to see a counselor.

The holiday season will be a sad and stressful one for our family. Christmas Eve we are going to the cemetery where Scott is buried to give him his present, a small artificial tree with battery operated lights. I don't look forward to this at all. I can't begin to tell you what a terrible feeling it is to watch your child deteriorate in front of your eyes and not be able to save him. I never knew that my child could die from eating a sloppy joe. God have mercy on this inadequate meat inspection system.

I want to address the issue of meat labelling. First of all, the labelling comes only as a settlement of a law suit filed by Jeremy Rifkin of Beyond Beef. It does not come out of the goodness of the F.S.I.S. hearts. Why did the U.S.D.A. wait until August of 1993 to attempt to implement labelling requirements for meat and poultry, when according to nationwide studies in 1985 and 1990, they were convinced of the need for more direct methods of placing food safety information in the hands of consumers? Why did the U.S.D.A. not follow proper procedures for rule making according to the Administrative Procedure Act? In reading a copy of the injunction Civil case #93-CA-586 in Austin, Texas, filed by various food associations, when the judge ruled against the labelling, the U.S.D.A. did not rebut the plaintiff's showing that an emergency does not exist to require an emergency rule. Does the U.S.D.A.

truly believe that this is not an emergency? Many children and elderly have died or been severely damaged already.

USDA's current labelling proposal is virtually meaningless. Nowhere does it state that the meat could contain bacteria that could lead to serious illness or death. In a transcript from a session with Secretary of Agriculture Espy, Assistant Secretary for Marketing and Inspection Branstool and Bob Sherwin, whose child was a victim in the Jack-in-the-Box poisoning, Mr. Sherwin stated, "Some consumer groups would like to tell people this may contain pathogens that could lead to so-and-so." Secretary Espy's reply was, "We wouldn't do that. I would suggest we would not do that. We would not want to have a chilling effect on meat sales with anything like that. This is not a product like cigarettes, but I think we have to tell the public about proper handling without suggesting that definite harm might result." I agree that this is not a product like cigarettes. Smoking takes a long period of time to cause permanent damage to a person's health whereas contaminated meat KILLED MY SON in 9 days. These statements made by Secretary Espy clearly reflect that he is more concerned with promoting the desires of the meat industry instead of being concerned with the safety of the American consumer.

The new labeling requirements tell to cook our meat thoroughly. I ask you where are the scientific studies to show at what temperature will kill all coliform levels? The U.S.D.A. has changed its cooking temperature requirements several times. My son is dead from eating a sloppy joe from a recipe that also says to

cook the meat thoroughly. Meat should be free from contamination and safe for consumption before it is allowed to be sold to the public.

One of today's big issues is health care cost. The medical bills I have incurred due to my son's illness caused by E.coli 0157:H7 is currently $40,000.00 and the bills keep rolling in. This is something that never should have happened to my son. This illness is preventable. No one should have to die or be injured because of consuming contaminated meat that was stamped U.S.D.A. approved.

The question I find myself asking is: USDA approved for what?

Mr. TOWNS. Ms. Heersink.

STATEMENT OF MARY HEERSINK, PARENT OF AN E. COLI 0157:H7 VICTIM, AND MEMBER, SAFE TABLES OUR PRIORITY

Ms. HEERSINK. Thank you for the opportunity to testify before you today.

Mr. Chairman, members of the committee, hemolytic uremic syndrome is a house on fire. It flashes from room to room, from organ system to organ system. There is no way to fully recount to you the searing torture my son endured during his 6½ weeks of intensive care, 20 months ago when he was 11 years old. But I will tell you about 1 day, not the worst day, just a day representative of the kind of burning danger this disease represents.

Our day began with relief. The gash on Damion's chest was knitting back together. The previous week he had undergone a heart surgery to save his heart from drowning in his own chest fluids. That surgery was now deemed to be a success even though it required the drastic measure of sawing open his rib cage and stripping the lining of his heart entirely away.

Damion now recognized us once again. He could stay awake for as long as 1 hour or 2 at a time. He was able to whisper when the respirator tubes were finally removed after 3 weeks on this life support.

He had not had anything by mouth for a month now and his thirst was really his greatest suffering during his disease course. But today the doctors felt that we could give him fluids for the first time to see if he could tolerate them.

After one sip of a drink, his intestines perforated. The surgeons determined once again they would have to open Damion back up, now his sixth surgery. We waited outside the operating room door while his intestines were unraveled, sewn back together where they had dissolved and packed back into his body.

This is only 1 day in a child's battle for life, an ordeal that began for my son when he ingested one bite of contaminated hamburger meat on an Alabama Boy Scout campout. Many people do not realize children with HUS often suffer lifelong complications.

For my son, he has a 30-percent lung tissue loss, no pericardium, a questionable immune system; and like all HUS children, faces a 30-percent chance of renal failure later in adolescent years. He has been rehospitalized with pneumonia and recurring pulmonary problems.

I am here today not only as a parent but as a member, a cochair of STOP, or Safe Tables Our Priority, along with other family members and friends of E. coli victims from around the country. I started STOP with others in response to the acute public health crisis faced in our country by foodborne illness.

Our umbrella organization, whose membership includes current and former USDA employees, has learned that 0157:H7 is only released into our beef supply when fecal matter, milk, and ingesta splatter on to cattle during careless slaughter and processing practices.

Secretary Espy may have had good intentions in his original zero tolerance directive put out in the wake of the Jack-in-the-Box dis-

aster, but what is important is how the directive filtered down to the frontlines of the inspection service.

STOP would like to describe to you what we would consider a responsible inspection system.

The several existing, and I say "existing" because the scientific technology does exist—probe technologies for 0157:H7 would be used in a creative manner, testing perhaps the herds for certification before slaughter; there would be a comprehensive trace-back system, an effective recall program. Inspection would run as a regulatory program. That means ongoing surprise inspections and financial penalties for abusers; compliance records would be open to the public; ineffective carcass sprays would become illegal; industry would consider it a civic duty to produce a clean product and understand that consumer confidence only results in better business and expansion of markets. Consumer education would essentially be unnecessary, because government would consider a safe product its responsibility and would institute hygiene and oversight measures to ensure consumer safety.

The primary difference with this inspection system would be that Federal inspectors, a hard-working group who only want to do a good job, would work in a regulatory agency, free of conflict of interest, where supervisors would back them up rather than overrule their decisions. The essential difference would be that inspection would be independent of business concerns and would operate as a public health program.

Thank you.

Mr. TOWNS. Thank you for your testimony.

[The prepared statement of Ms. Heersink follows:]

STATEMENT OF MARY HEERSINK
BEFORE THE HOUSE SUBCOMMITTEE ON HUMAN RESOURCES
AND INTERGOVERNMENTAL RELATIONS
COMMITTEE ON GOVERNMENT OPERATIONS
November 4, 1993

The disease Hemolytic Uremic Syndrome (H.U.S.) ravages the human body like a fire ravages a house. It is equally as horrifying to be told by the doctors that your son has H.U.S. as it is to be told by fire fighters that your son is trapped inside your burning home. H.U.S. is a fire that blazes through the house of your child's body. It flashes from room to room, from organ system to organ system. Sometimes its scorching destruction is limited to a child's colon, or his kidneys. But all too often it erupts in other organs, gutting entire sections of your child's life, leaving him blind, or diabetic, or stroke-damaged.... the possible consequences are endless and horrific because any room can burst into flames.

They tell you it is impossible to predict how long this fire will burn. A fire is extinguished in one room. But the doctors do not allow you to rejoice because they know that just as soon as one life-threatening fire is dampened, others may explode. As a parent, all you can do is to stand nearby and watch.

There is no way to fully recount the searing torture that my son, Damion, endured during 6 1/2 weeks of pediatric intensive care two years ago when he was only 11 years old. But I'll tell you about one day, not even the most awful day, just a day representative of the burning danger and damage that a child battling H.U.S. faces.

The day began with relief and hopeful anticipation. The

surgeon's gash on Damion's chest was knitting itself back together. The previous week he underwent a fourth surgical procedure to save his heart from drowning in his own chest fluids. That surgery was a success, even though it had required the drastic measure of sawing open his rib cage and stripping the lining of his heart entirely away.

On this day his fever was subsiding. The chest tubes poured out a thinner, clearer fluid now. His kidneys finally resumed their work, allowing the dialysis machine to be disconnected from the catheter that punctured his abdomen. His heart rate and blood pressure were high but not as alarming as they had been for weeks. The bloody diarrhea and hemorrhaging from his bowel had finally stopped. He recognized us once again. He could stay awake for as long as an hour or two at a time now. He was able to whisper when the respirator tubes were finally removed after three weeks on life support.

His thirst had burned in his mouth for a month. Not being able to take fluids let alone food by mouth since his hospitalization had been his greatest suffering. He hallucinated about fluids, cried and begged for them, had to be tied down to his bed because he believed we were conspiring to keep him from drinking, and he even tried to rip out his IV lines so he could reach the sink in the corner of the hospital unit. This day the doctors felt we could see whether his gastrointestinal tract could tolerate clear liquids. Damion had fantasized for weeks about a frozen drink from a Seven Eleven store. I purchased his favorite drink, thrilled to be able to give him something he

craved. My husband gave him one sip from the straw. I gave him the second drink a moment later. We watched in horror as he blanched white in pain. For the first time, Damion used his pain pump, an urgent dose of morphine, before he fell into a drugged sleep.

His father and I spent the afternoon convincing the nursing staff that the drink had perforated his intestines. That evening his temperature soared. The surgeon determined that once again he would have to open up Damion's body. We waited outside the operating room while Damion's intestines were unraveled, sewn together where they had dissolved, and packed back into his body.

This was only one day of Damion's ordeal. An ordeal that began when he ate a small chunk of undercooked hamburger contaminated with the bacteria E. coli 0157:H7 at an Alabama Boy Scout picnic. An ordeal that continues to this day. Many people do not realize that if a child survives H.U.S. they may experience lifelong complications. Damion has permanently lost 30% of his lung tissue, he has no pericardial sac or heart lining, he faces 10 years of uncertainty whether he will become HIV positive from the massive blood products he received, and he will have a lifelong battle fighting illness because his immune system has been compromised. Already he has been re-hospitalized with pneumonia and has had recurring pulmonary problems.

I am here today not only as a parent retelling a story of personal tragedy, but also as a founder and co-chair of S.T.O.P., or Safe Tables Our Priority. Along with other family members and

friends of E. coli victims from around the country, I founded S.T.O.P. in response to the acute public health crises caused by food-borne illness. In June of this year, approximately 20 people representing 10 states and the District of Columbia, and a number of grassroots organizations all gathered in Kansas City to compare wrenching personal tragedies of how our loved ones had suffered, and often died, from eating E. coli-contaminated hamburger and subsequently contracting H.U.S. We discovered that we shared frustration over the lack of responsibility and accountability of the local, state, and federal agencies overseeing food inspection and public health problems involved with food-borne illnesses. We agreed that no one should have to suffer the horror of H.U.S. caused by E. coli-contaminated beef, particularly when this bacterial contamination is avoidable.

Our umbrella organization, whose membership also includes current and former USDA employees, has learned that E.coli 0157:H7 lives naturally in the intestinal tracts of cattle. This killer bacteria is only released into our beef supply when milk, ingesta (the stomach contents), or fecal material gets on the meat itself as the result of careless slaughter and processing practices. We have also learned that there were 16 outbreaks of illness from E. coli-contaminated beef in the 10 years before the Jack-in-the-Box tragedy of last winter -- and the United States Department of Agriculture knew about every one!

We have been told by medical experts and scientists that 10 years ago H.U.S. was a rare disease. Now H.U.S. is the leading

cause of renal failure for children in the U.S. and up to 95% of the post-diarrheal H.U.S. cases are caused by E. coli 0157:H7.[1] By USDA's own estimates, up to 20,448 infections and nearly 389 deaths are caused by E. coli 0157:H7 annually.[2] Don't think that children who eat fast food hamburgers are the only ones at risk. Our members' children have eaten ground beef cooked at home, at picnics, while camping, as well as at fast food chains. Some children have contracted E. coli-caused H.U.S. as secondary transmissions from family members and at daycare centers. We've learned that the elderly are also at risk as are health care workers in hospitals. And we all know, only too well, that there is no certain treatment - no cure - for H.U.S.

Secretary Espy may have had good intentions in his original zero tolerance directive put out in the wake of the Jack-in-the-Box disaster. But good intentions aside, what is important is how this directive filtered down to the front lines of the inspection service. There is an internal industry memo shared with us by the Government Accountability Project (a whistleblower support organization) that refers to a meeting held between industry representatives and FSIS Administrator Dr. H. Russell Cross that explains the zero tolerance policy "is for 'obvious' fecal and ingesta contamination ... if the inspectors are calling non-obvious specks, they need to be challenged." The memo goes on suggesting that Dr. Cross requested industry to "please keep [USDA] informed and it would not hurt to provide me with names of inspectors who seem to get out of line on this."[3] S.T.O.P.

parents who have witnessed first hand just what fecal contamination can do to an otherwise healthy child are outraged by these cynical instructions issued by FSIS.

The USDA's recently released Clean Carcass Emphasis Production Program (CCEPP) is more of the same. In its first released form CCEPP actually proposed that any fecal contamination spots less than 1/4 inch were unidentifiable and should not be interpreted as fecal contamination.[4] Though FSIS rescinded that portion of the document, S.T.O.P. cannot understand how any agency upholding a human health agenda would ever propose such a directive in the first place.

The more S.T.O.P. learns about USDA, the less confident we are in its ability to address the problem of bacterial contamination in meat. We believe that the division within USDA responsible for both the promotion of agricultural products and the inspection of meat and poultry has an inherent conflict of interest that is even reflected in its very name, "Marketing and Inspection."

USDA released a report that it had conducted a series of 90 surprise inspections in March of beef slaughterhouses after which USDA temporarily shut down 30 of the 90 plants for "unacceptable conditions", recorded negative findings in an additional 34, and was only able to clear 26 of the total 90 plants visited. Many of us saw the CBS television news program "Eye on America" that aired on May 17, revealing the shocking filth in one plant allowed by USDA to contaminate our meat supply. CBS later

reported that the plant shown on television was temporarily shut down by USDA. But the plant was not one of the 90 USDA reviewed in its investigation. S.T.O.P. members want to know: What about the other 1,110 cattle slaughter plants operating in the U.S.?

It is logical to think that any inspection service that polices a product would have the ability to recall when a bad product is found. However, USDA does not, and the agency did not even use the voluntary recall authority it does have when large quantities of E. coli 0157:H7 contaminated hamburgers were identified in Seattle during the Jack-in-the-Box outbreak. In a conversation between Charles Bartleson of the Washington State Health Department and Dr. Jill Hollingsworth of the Food Safety and Inspection Service at USDA, he was told "We will take no action [with regard to recalling the hamburgers] because this meat does not violate the USDA standards." Mr. Bartleson replied, "I thought you guys were in the public health business."[5]

Although many S.T.O.P. members are human health experts, it does not take a medical or science background to realize that some of what USDA regards as permissible defies common sense. For example, common sense dictates that we should not allow feces to smear, splatter, or be embedded in our meat. USDA provided us with a study explaining that faster line speeds in the slaughter plants don't just permit plants to increase their profits but that those line speeds actually make the meat safer by racing it into the cooler.[6] Sure, refrigeration slows down bacterial

growth, but refrigeration won't kill E. coli 0157:H7. Neither, in fact, will freezing. Only temperatures -- some say as high as 160° F will kill this killer.

Common sense dictates that any inspection service for public health needs a human health professional to direct it. Yet USDA - FSIS does not have one human health professional in its senior management. Let me give you an example of how the lack of human health experts at USDA is perceived by S.T.O.P. In a letter to one of our members from former Acting Assistant Secretary for Marketing and Inspection Kenneth Clayton, he referred to H.U.S. as merely "a urinary tract infection." When I later met with him in person, he was unable to even name the disease caused by E. coli. I left that meeting thinking, "is there no one at FSIS in touch with the Centers for Disease Control and Prevention?"

S.T.O.P. would like to describe to you what we would consider a responsible, intelligent inspection system. E. coli 0157:H7 and other pathogens contaminating meat would lead it to be officially classified as adulterated. This system would utilize several existing 0157:H7 probe technologies in a creative way - testing the herd populations, for instance and random ongoing testing of retail samples. There would be a comprehensive traceback system and an effective recall program for any contaminated product. Inspection would run as a regulatory program that would include ongoing surprise inspections and financial penalties for abuses. Compliance

records would be open to the public. Ineffective acid washes and carcass sprays would be illegal. Industry would consider it a civic duty to produce a clean product and would understand that consumer confidence results in more business and the expansion of markets. Americans could still enjoy rare meat, even steak tartare. Massive consumer education projects would be unnecessary because the government would consider an uncontaminated product its responsibility and would institute hygiene and oversight measures to ensure that consumer safety is protected. The incidence of H.U.S. would decline dramatically. The highest levels of the meat and poultry inspection service would be peopled with medical and food microbiology experts. There would be a keen appreciation for the relationship between policy, pathogens, and human illness at the highest echelons of the inspection service. The federal inspectors, an honest and hard-working group of federal employees who want to do a good job, would work in a regulatory agency without conflict of interest, where supervisors back them up rather than overruling their inspection dispositions. The most profound difference would be that meat inspection would be independent of business concerns and would operate as a public health program.

Until these criteria are met by our meat inspection system, E. coli 0157:H7 will continue to be a bacterial spark smoldering in America's meat supply. Isn't it time to take away the matches?

1. Griffin, Patricia, and Tauxe, Robert. "The Epidemiology of Infection Caused by Escherichia coli 0157:H7, other Enterohemorrhagic E. coli, and the Associated Hemolytic Uremic Syndrome." American Journal of Epidemiology, 1991 13:60-98.

2. *Federal Register*, Vol. 58, No. 156, 8-16-93 Table 1 - Estimated Annual Costs for Selected Foodborne Pathogens, 1992, p. 43478.

3. Cargill Memo from Dell Allen, Re: zero tolerance interpretation problem with USDA, 3/5/93.

4. Clean Carcass Emphasis Production program, Draft September 3, 1993, "Defect Identification Guidelines - meat", p. 7 (of 7 pages sent on Clean Carcass Emphasis Production Program.)

5. Document #1710.3 in file notes of the Washington State Health Department. Telephone conference notes from 1/26/93, at 7:12 a.m.

6. Hogue, Alan, et al. Bacteria on Beef Briskets and Ground Beef: Correlation with Slaughter Volume and Antemortem Condemnation, F.S.I.S. Science & Technology, Slaughter Inspection Standards and Procedures Division, Feb. 19, 1993.

Mr. TOWNS. Dr. Marcuse.

STATEMENT OF EDGAR K. MARCUSE, M.D., PEDIATRICIAN, CHILDREN'S HOSPITAL AND MEDICAL CENTER, SEATTLE, WA

Dr. MARCUSE. I am a pediatrician in Seattle's Children's Hospital. I have been asked to describe the disease caused by E. coli 0157:H7 and review the outbreak of E. coli disease that struck Seattle last January, and outline Federal actions that could reduce the risk of such outbreaks.

First, how does E. coli cause such serious disease? Common strains of E. coli live in the intestines of healthy animals and people. Other strains cause simple illnesses such as "traveler's diarrhea."

The strain 0157:H7 produces a toxin that can cause bloody diarrhea and abdominal cramps. Most patients recover in a few days without specific treatment, but about 15 percent go on to develop a serious, sometimes life threatening, complication called hemolytic uremic syndrome or HUS. HUS affects the kidneys and the blood clotting system, and in about half the cases, kidney failure develops and dialysis is required, at least temporarily.

Most cases of HUS are due to E. coli 0157:H7. Contamination of meat may occur as a normal part of the slaughtering process; if the meat is then not properly refrigerated, bacteria rapidly multiply; and if the meat is not fully cooked, they can survive and infect. These bacteria are present in the stool of infected persons and can be passed from person to person.

Let me now describe what happened last January in Seattle. On January 7, a little girl from a Seattle suburb was brought to her pediatrician's office because of bloody diarrhea. As a matter of routine, he tested her stool for E. coli 0157:H7.

Before the results were back, a second child was presented to the same office, and he then called my hospital's pediatric gastroenterologists. The first girl developed kidney failure 2 days later, and was hospitalized for dialysis. Within 24 hours, three other children were seen in our emergency room for bloody diarrhea and other physicians called our hospital gastroenterologists.

On January 12, 2 days before the culture results were confirmed, Dr. Phil Tarr, a pediatric gastroenterologist and E. coli researcher, called State health officials to alert them to the possibility of an outbreak. Within 5 days, health department officials confirmed an outbreak of foodborne E. coli 0157:H7 was in progress and alerted the public.

A day later, they traced the outbreak to undercooked contaminated hamburger served in a Seattle Jack-in-the-Box Restaurant. A month later, a total of 500 confirmed cases had been reported and 45 children had been hospitalized at Children's for complicated disease, of whom three subsequently died, a 2-year-old boy, a 2-year-old girl, and a 17-month-old boy.

The total impact of this tragedy is impossible to tally. The hospital bills for those 45 children totaled over $2 million. The cost per child averaged $27,000, excluding the bills for one child, Sara Kiner, who was discharged after 152 days, 5 months, at a total cost of over $750,000.

Caring for so many seriously ill children was an enormous challenge. Our dialysis service performed 132 treatments in 3 weeks, compared to the usual pace of about 30 per month. Our hospital was the center of this outbreak because we are the only regional institution with the skilled staff and resources these really sick children required.

It was a very difficult time for parents. Our nurses answered over 7,000 calls in January. Imagine the worry of a parent whose child developed a stomachache during this time or who had a hamburger, who attended daycare with a child who was ill. Every parent, every daycare, every restaurant was affected.

Within the last 2 weeks in Washington State and Idaho, 12 cases of E. coli have occurred. They are now under investigation. At the time of this hearing, two children are hospitalized at my hospital for treatment of HUS.

What could the Federal Government do to reduce the risk of such outbreaks? First, you could support research to understand the biology of this strain of E. coli, how it infects cattle, where it exists in nature, what factors favor its growth. This kind of work may show us how to prevent colonization in cattle.

Second, you should take steps to limit further the fecal spillage that occurs during slaughter and to ensure that proper cooling and refrigeration practices are followed and you should look seriously at other methods of limiting bacterial growth in foods such as irradiation.

Third, you should use education and regulation: Education to increase the public's understanding that all raw foods of animal origin must be properly handled and fully cooked to avoid infection, and regulation to be sure that all commercial hamburger patties are cooked to 155 degrees.

I would like to add one additional thought. We had the needed expertise because Seattle's Children's Hospital is a regional teaching and research center. As you design our Nation's new health care system, please remember this outbreak. Resources must be preserved to do needed research, train specialists, and maintain access to regional tertiary care centers.

Spending for children's health care and related research accounts for a very small part of the total U.S. health care research dollars. We must be able both to respond to outbreaks like this in the future and to learn how to prevent them.

[The prepared statement of Dr. Marcuse follows:]

Children's

Testimony Before the House Government Operations Committee, Subcommittee on Human Resources and Intergovernmental Relations

Presented by:
Edgar K. Marcuse, MD, MPH, FAAP

November 4, 1993

My name is Ed Marcuse, M.D. I am a pediatrician at Children's Hospital and Medical Center in Seattle, Washington. I have been asked (1) to describe the disease caused by E.coli 0157.H7 and its complications; (2) to review the impact on our community and hospital of last winter's outbreak; and (3) to outline, from a health care provider's perspective, recommendations for federal government actions to prevent future outbreaks of foodborne E.coli 0157:H7.

This outbreak became the largest, certainly the most publicized, and I believe, the best investigated outbreak of E.coli disease associated with hemolytic uremic syndrome (HUS). Forty-five children were hospitalized at Children's Hospital and Medical Center and three died of complications related to E.coli 0157:H7 disease. The total number of confirmed cases reached 500. The response to this emergency was a model of cooperation among Children's Hospital staff, local, state and federal public health authorities, other hospitals and community physicians who rapidly recognized and worked to limit and manage the outbreak.

The outbreak could have been more widespread and far more tragic. Dr. Phil Tarr, a Children's gastroenterologist and E.coli researcher, suspected an outbreak very early in its course and alerted the State Health Department which made possible prompt action to confirm and assess the outbreak and develop a coordinated control strategy. Children's medical, surgical, emergency, intensive care, dialysis services', community relations' and the Health Department's response to the escalating crisis was crucial in averting additional deaths and limiting panic.

WHAT IS E.COLI 1057:H7?

E.coli is a bacteria that normally lives in the intestines of healthy humans and animals. Common strains of this bacteria are part of the gut's normal flora. Some strains cause simple traveler's diarrhea. The E.coli strain, known as 0157:H7, produces a toxin which can cause bloody diarrhea and abdominal cramps. Most patients recover in a few days without any specific treatment, but some develop life threatening complications.

Contamination of meat with E.coli bacteria may occur as a normal part of the slaughtering process. If meat is not rapidly cooled and kept refrigerated, the bacteria will multiply. These bacteria will be killed if meat is thoroughly cooked, but may survive in rare or inadequately cooked meat. Bacteria present in the stool of infected persons may be passed from person to

person.

Hemolytic uremic syndrome is a serious disease that affects the kidneys and the blood clotting system. Most cases of HUS in the Pacific Northwest are caused by E.coli 0157:H7. In severe cases, kidney failure develops and dialysis is needed to take over the function of the kidneys, usually temporarily. Serious long term kidney complications develop in 10% to 20% of those affected acutely. Other complications of HUS include bleeding, seizures, intestinal perforation and heart failure. The disease's severity varies: the majority of people infected with this bacteria do not develop HUS. Fortunately, it is a rare complication, but it is more common in children than in adults.

CHILDREN'S HOSPITAL AND MEDICAL CENTER'S INVOLVEMENT IN THE IDENTIFICATION OF THE OUTBREAK

On January 7, 1993, a little girl came into a Richmond Beach, Washington pediatrician's office with bloody diarrhea. As a matter of routine, her doctor tested the child's stool for E.coli 0157:H7. Before the results were back, a second child with bloody diarrhea came to the same pediatric practice. These pediatricians consulted with Children's gastroenterologists, Drs. Phil Tarr and Dennis Christie.

On January 9, the first little girl from Richmond Beach developed kidney failure and was admitted to Children's for dialysis.

Other community physicians called Children's gastroenterologists about other children with bloody diarrhea and Children's Emergency Department physicians treated three children for bloody diarrhea within a 24-hour period.

On January 12, *two days before the presence of the bacteria had been confirmed,* Dr. Tarr called Dr. John Kobayashi, Washington Department of Health epidemiologist, to alert him to a possible E.coli 0157:H7 outbreak.

State health authorities began alerting area emergency rooms to culture children with bloody diarrhea for E.coli 0157:H7. On January 17, the State Health Department had sufficient information to focus its investigation on Jack-in-the-Box restaurants and to alert the public to the outbreak. The following day, the State Health Department reported that its investigation had linked the disease to eating undercooked hamburgers which had been prepared from meat contaminated with the bacteria and served by Seattle area Jack-in-the-Box restaurants.

By this time, Children's Hospital and Medical Center was treating 12 patients with E.coli related disease including two who required intensive care. Subsequently, three of 45 Children's patients died: a two-year old boy, a two-year old girl, and a 17-month old boy. By February 20 a total of 500 cases of E.coli

0157:H7 disease had been reported to the State Health Department.

IMPACT OF THE OUTBREAK ON CHILDREN'S HOSPITAL AND THE COMMUNITY

The total impact and cost of this outbreak is impossible to measure, however the total charges of the 45 children who were hospitalized was nearly $2 million. The cost per child hospitalized ranged from $632 to $158,000 and averaged $27,000 excluding one child who was discharged after 152 days (5 months) at a cost of over $725,000.

The outbreak affected virtually every hospital department.

Inpatient Units

Thirty-seven patients developed kidney complications of HUS and 21 required dialysis. Dialysis nurses worked 14-hour shifts and performed five times the usual number of dialysis runs, stepping over tubes and wires stretched across the halls, so that three children in the Pediatric Intensive Care Unit could be on dialysis at the same time. One hundred thirty-two dialysis treatments were performed by the Nephrology Service in three weeks compared with the service's usual pace of 30 treatments per month!

Emergency Room:

Approximately 350 children with diarrhea and fever were evaluated for possible E.coli disease. Ninety had bloody diarrhea; 60 were treated as outpatients and 30 were admitted.

Laboratory:

During January, 30 to 50 stool samples were processed per day, compared to the usual 5 samples per day. The laboratory worked around the clock and set up an assembly line to screen for E.coli.

Children's Resource Center:

Resource Telephone Line nurses answered 7,000 calls during the month of January, 3,000 more than normal.

Children's Hospital was the center of this outbreak because it was the only regional institution which had the resources and skilled staff these children required, but the entire community was impacted. The daily newspapers and nightly news provided the community with accurate information. Physicians' offices were deluged by calls and visits from worried parents. Imagine the worry of a parent whose child simply developed a stomach ache last January in Seattle; or the parent whose child had a hamburger at an implicated restaurant or went to day care with a child now hospitalized for HUS. Every parent, every day care, every doctors' office, every restaurant was affected.

PREVENTING FUTURE E.COLI 0157:H7 OUTBREAKS

How might we prevent such outbreaks of foodborne illness due to E.coli 0157:H7? What could the federal government do?

First, and most importantly, we must support research to

understand the biology, ecology and epidemiology of this bacteria: where it exists in nature, what enhances its growth compared to strains that do not cause disease, and how it is transmitted to food animals. Such research may point the way to preventing colonization in cattle.

Children's Hospital and Medical Center, the University of Washington, and the Washington State University have all been collaborating epidemiologically and biotechnologically to get the organism out of the food supply. Funding for these efforts have been and continue to be meager.

Second, we should take steps now to (a) limit the contamination of foods by reducing to the minimum possible fecal spillage during slaughter and processing, (b) assure that water used to clean carcasses is pure, and (c) seriously investigate the utility of other methods of limiting bacterial contamination such as irradiation.

Third, we should use education and regulation to increase the public's understanding that in the U.S. today all raw foods of animal origin must be properly handled, adequately refrigerated and cooked to avoid infection and ensure all commercial hamburger patties are cooked to a temperature of 155°F.

By 1987, we knew that (a) E.coli 1057:H7 could cause disease, (b)

that the disease could be sporadic or epidemic, (c) that severity varied from mild self-limited illness to severe, life-threatening disease. We also know that (d) the organism could be transmitted by inadequately cooked foods of animal origin and, (e) that cattle were colonized with it. Therefore, as long ago as 5 years before this tragic and costly outbreak, we had the opportunity to take all the steps I have just recommended.

CONCLUSION

We at Children's Hospital and Medical Center were privileged to be able to respond to our community's need. In so doing, we fulfilled both our institutional, professional and personal missions of care, education, research and child advocacy. We had the needed expertise because we are a regional, teaching and research institution.

As you design our nation's new health care system, resources must be preserved to support research, to train future specialists and to preserve access to regional pediatric tertiary care centers. The need to ensure access to primary care for all Americans is widely recognized. This outbreak makes crystal clear the need for pediatric specialists, the utility of a regional pediatric center and the value and importance of pediatric research. Today in the U.S., there exists a shortage of some types of pediatric subspecialists. Spending for children's health care and related research accounts for a very small proportion of the total U.S.

health care and research dollars. As we proceed in reforming our health care system, we must preserve the resources necessary both to respond to and to learn how to prevent a tragic outbreak such as this.

Thank you for your attention.

Mr. TOWNS. Dr. Blake.

STATEMENT OF PAUL A. BLAKE, M.D., DIVISION OF BACTERIAL AND MYCOTIC DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. PUBLIC HEALTH SERVICE

Dr. BLAKE. I am Paul Blake of the Centers for Disease Control and Prevention. I am pleased to respond to the committee's invitation to discuss CDC's role in preventing foodborne disease. This is a common public health problem with estimates of over 80 million foodborne illnesses each year in the United States.

CDC has unique capabilities in foodborne disease control and prevention that are complementary to the roles of FDA and USDA. CDC's primary role is risk assessment in a matrix that addresses a wide range of threats to the Nation's health, some of which are foodborne.

CDC has developed five tools for foodborne disease risk assessment.

First, isolations of potential foodborne pathogens are reported weekly through State public health laboratories to CDC. In August, these data helped describe the spread of an interstate outbreak of salmonella montevideo infections traced to contaminated tomatoes.

Second, CDC staff can respond rapidly to disease outbreaks. Initially, we do not know if the disease is foodborne. In January, 5 CDC field teams with 14 medical and veterinary epidemiologists supported by CDC laboratories, worked with State and local officials to investigate a large E. coli 0157:H7 outbreak. Well over 500 people were infected, 4 died, and 48 developed a serious complication, the hemolytic uremic syndrome.

These investigations traced the infections to eating hamburger. They led to recall of the contaminated hamburger, preventing many cases; new cooking requirements for hamburgers; intense scrutiny of the slaughter and processing practices that may contaminate meat; and identification of the factors which facilitate person-to-person transmission of this infection in child-care centers.

Third, the foodborne disease outbreak surveillance system collects reports of outbreaks investigated by local and State health departments. These data have been exceedingly useful in learning about specific pathogens and foods.

For example, when we suspected eggs were causing a marked increase in salmonella enteritidis infections in the Northeastern United States, a review of State foodborne outbreak reports for the previous decade showed that salmonella enteritidis outbreaks were strongly associated with egg-containing foods. This helped stimulate a joint State, Federal, and industry effort to prevent these infections.

Fourth, investigations of sporadic cases of specific foodborne diseases are important because most foodborne illnesses occur as scattered cases, apparently not related to outbreaks. Control of outbreaks alone may not control sporadic cases. For example, although campylobacter outbreaks are often caused by raw milk, most campylobacter sporadic cases are caused by poultry.

Fifth, laboratory analysis of bacteria submitted for reference diagnostics is crucial in preventing foodborne diseases. Now, we can often distinguish the outbreak strain from other similar

strains, and thus track the outbreak strain all the way back to the source.

Four activities will lead to better control of foodborne disease.

First, closer coordination with the risk management agencies and the States.

Second, strengthened public health surveillance of foodborne disease at the Federal, State, and local levels.

Third, rapid and effective reaction to foodborne disease. Rapid electronic reporting of foodborne pathogens by States and rapid laboratory examination of pathogens permits rapid action by CDC in cooperation with the States, FDA, and USDA.

Fourth, more proactive rather than reactive foodborne disease prevention programs. Modern efforts to control foodborne disease emphasize identifying and monitoring the critical points in the food production chain where problems can occur. CDC's foodborne disease activities help identify these critical control points.

In summary, CDC's role in food safety issues is complementary to those of FDA, USDA, and the State and local authorities.

Thank you.

I would be happy to answer any questions.

[The prepared statement of Dr. Blake follows:]

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Public Health Service

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Statement of

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Division of Bacterial and Mycotic Diseases

National Center for Infectious Diseases

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Public Health Service

Department of Health and Human Services

before the

Subcommittee on Human Resources

and Intergovernmental Relations

Committee on Government Operations

U.S. House of Representatives

November 4, 1993

I am Paul A. Blake, M.D., M.P.H., Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). I am pleased to respond to the Subcommittee's invitation to discuss foodborne disease surveillance and CDC's role in preventing foodborne disease in the United States. In my testimony I will review the methods CDC uses to identify foodborne disease hazards and characterize the risk of illness associated with those hazards.

Foodborne disease is a common and preventable public health problem, with estimates of over 80 million foodborne illnesses each year in the United States. Foodborne illness can be mild or life-threatening, causing miscarriage, hemolytic uremic syndrome (HUS), chronic kidney disease, arthritis, and death. Available data indicate that most foodborne disease is caused by bacteria which enter food preparation areas on foods of animal origin. These bacteria can then be spread to other foods and multiply. Traditional inspection methods do not detect the contaminating bacteria.

During the past 2 decades CDC has learned a great deal about foodborne disease. For example, we have found that previously obscure bacteria such as Campylobacter, Listeria, and E. coli 0157:H7 are important causes of foodborne disease. We have recognized that outbreaks of foodborne salmonellosis, which have traditionally been associated with meat and poultry, can also be caused by contaminated tomatoes and melons. Foodborne disease is an evolving public health challenge--a problem of emerging infectious disease. The recent Institute of Medicine (IOM) report, "Emerging Infections," identifies a number of factors which can lead to emerging microbial threats, and all of these factors have impacted on the safety of our food supply. I would like to submit a copy of the Executive Summary of the IOM report for the record.

Prevention of foodborne disease requires a coordinated program of risk assessment to identify the causes of illness and determine how often and under what circumstances illness occurs, and risk management which combines educational and regulatory responses to prevent disease. FDA and USDA have regulatory authority for protecting the safety of the nation's food supply. CDC has unique capabilities in foodborne disease control and prevention that are complementary to the roles of FDA and USDA. CDC's primary role in the coordinated federal program to prevent foodborne disease is that of risk assessment. CDC defines which microorganisms are serving as foodborne pathogens, characterizes foodborne illness epidemiologically and clinically, identifies risk factors for infection, and provides prevention recommendations.

As the nation's prevention agency, CDC has the knowledge, skills, and perspective critical to flexible and unbiased, science-based programs for disease surveillance, outbreak investigation, and prevention. These public health programs

exist in a matrix that addresses a wide range of threats to the nation's health, some of which are foodborne.

These are tools CDC has developed for risk assessment of foodborne disease:

1. **Laboratory-based surveillance for foodborne pathogens**

Individual isolates of potential foodborne pathogens such as Salmonella, Shigella, and Campylobacter are reported through state public health laboratories to CDC. These data identify outbreaks and specific strains that need further investigation, warn us about introduction of new strains in food animals, and track the spread of epidemics. For example, earlier this year these data helped delineate the course and geographic spread of an interstate outbreak of Salmonella montevideo infections traced to contaminated tomatoes. Public health officials at the local, state, and national levels use CDC data to recommend prevention measures.

2. **Outbreak investigations**

CDC maintains a staff of epidemiologists, microbiologists, environmental and other scientists, who can respond rapidly to disease outbreaks of unknown origin. Some of the outbreaks may be associated with foodborne pathogens, such as the large interstate outbreak earlier this year of E. coli 0157:H7 infections; however, many outbreaks are associated with other pathogenic or environmental agents unrelated to food. Such outbreaks require rigorous epidemiologic and laboratory based investigations to determine underlying causes of disease and routes of transmission. It is not always possible to know at the outset that the disease is foodborne.

CDC investigations of hamburger-associated outbreaks in 1982 provided the first identification of E. coli 0157:H7 as a foodborne pathogen and much of what is known about this emerging public health threat has been learned during outbreak investigations. In the E. coli 0157:H7 outbreak earlier this year, five CDC field teams with 14 medical and veterinary epidemiologists supported by CDC laboratories worked with state and local public health officials to investigate causes of the outbreak. Well over 500 people were infected, four died, and 48 developed a serious complication, the hemolytic uremic syndrome. Information from the investigations was shared with local, state, and federal agencies. These investigations traced infections to eating hamburger. They led to 1) rapid recall of the contaminated hamburger, limiting the size of the outbreak; 2) new cooking requirements for hamburgers; 3) intense

scrutiny of slaughter and processing practices that may increase contamination of meat; and 4) identification of factors which facilitate person-to-person spread of infection in child care centers.

3. **Foodborne disease outbreak surveillance system**

Most foodborne disease outbreaks are investigated by local and state health departments, which send CDC summaries of their results. These data have been exceedingly useful in learning about the roles of specific pathogens and foods in causing foodborne disease in the United States.

For example, in the mid-1980's laboratory-based surveillance showed us that there was a marked increase in the incidence of Salmonella enteritidis infections in the northeastern United States. Investigations led us to suspect that the source was organisms that entered chicken eggs before they were laid. We reviewed the foodborne outbreak reports from the states for the previous decade and found that Salmonella enteritidis outbreaks were strongly associated with egg-containing foods. These findings helped stimulate creation of a joint effort by state and federal agencies and industry to prevent and control these infections.

Outbreak surveillance data also help CDC evaluate the impact of control measures. For example, in 1979-1981, a series of Salmonella outbreaks were traced to commercial pre-cooked roast beef. USDA cooking regulations were changed, and the surveillance data have shown that the new regulations were effective in preventing and controlling outbreaks caused by pre-cooked roast beef.

4. **Studies of specific foodborne diseases**

Much of our understanding of foodborne disease comes from investigations of sporadic cases of illnesses of unknown causes. Although outbreaks get attention, most foodborne illnesses occur as scattered cases apparently unrelated to outbreaks. Outbreak cases and sporadic cases caused by the same pathogen can be associated with different foods and require different preventive measures.

For example, CDC found that almost half of the foodborne outbreaks caused by Campylobacter were caused by drinking raw milk. However, most of the estimated 2 million Campylobacter infections in the United States each year are sporadic cases. Studies by CDC and others suggest that the food that causes most sporadic cases is poultry, not raw milk. In sporadic Campylobacter infections in a Seattle health maintenance organization, at least 50% were accounted for by poultry. Among university students in Georgia, 70%

of sporadic cases were associated with eating chicken, often undercooked or raw. Thus, in order to accurately identify risk factors for foodborne infections and design prevention and control strategies, CDC needs to assess sporadic foodborne illnesses as well as outbreaks.

Another example is CDC's approach to the problem of sporadic infections caused by Listeria, which was only recently discovered to be foodborne. CDC epidemiologic and laboratory investigations of sporadic cases found that eating soft cheeses, undercooked chicken or hot dogs, and food purchased from delicatessens were associated with listeriosis. In one instance, Listeria organisms of the same rare subtype were isolated from a patient, an opened package of hot dogs in her refrigerator, unopened packages from the store and the plant, and the plant environment. These studies led to specific recommendations for producers, consumers, and physicians to prevent this disease.

5. Analyzing isolates submitted for reference diagnostics

CDC's laboratory expertise is crucial to understanding and preventing foodborne disease. Not only do the laboratories identify known pathogens and discover previously unknown pathogens, but they use a wide variety of methods to subtype apparently identical organisms. This has proved to be enormously important, because now we can often distinguish the outbreak strain from other strains of the same pathogen, and thus track the outbreak strain all the way back to the source. Such evidence is important to the regulatory agencies in deciding on effective control measures.

Despite our successes, the continued presence of hazards in our food supply show us that we must do better. We have identified four activities that will lead to better control of foodborne disease. These activities are dependent upon adequate resources at the federal, state, and local levels.

1. Closer coordination with risk management agencies and the States

CDC works closely with State health departments and with FDA and USDA to control foodborne disease. CDC and FDA have a long history of collaborative activities. The USDA's Animal and Plant Health Inspection Service (APHIS) has assigned a veterinary epidemiologist to CDC; this has enhanced our ability to track foodborne disease problems back to problems in livestock and poultry production. USDA's Food Safety and Inspection Service (FSIS) will soon assign a veterinarian to CDC, which should enhance our ability to investigate the slaughter and processing environment.

2. **Strengthened surveillance for emerging human pathogens**

Effective public health surveillance of foodborne disease at the federal, state, and local levels, including increased laboratory capacity, is key to developing, implementing, and evaluating prevention and control policies. As emphasized in the IOM report, "Emerging Infections," strengthened surveillance capacity is critical to the recognition and control of infectious diseases. CDC is developing electronic systems that will make reporting of recognized and emerging foodborne pathogens by state health departments to CDC easier and faster.

3. **Rapid and effective reaction to foodborne disease**

With rapid electronic reporting of foodborne pathogens by states, CDC can analyze the data immediately and take appropriate action in cooperation with the states, FDA, and USDA. CDC has developed a computer-based data management and reporting system, the Public Health Laboratory Information System, and is developing software modules for foodborne pathogens. CDC is assisting states in installing this system in all public health laboratories. Another increasingly important element in foodborne disease control is rapid transport to CDC of pathogens for detailed subtyping, which can often help clarify confusing situations.

4. **More proactive rather than reactive foodborne disease prevention programs**

Modern efforts to control foodborne disease are turning away from simply inspecting the final food product, which can never detect every hazardous food item. Increasingly, the emphasis is on identifying the critical points in the food production chain where problems can occur, and focusing attention on those critical control points to ensure a safe final product. CDC's foodborne disease activities help identify these critical control points.

In the longer term, to more completely identify foodborne hazards, characterize their risk, and help set foodborne disease prevention priorities, an expanded surveillance program would be necessary to include additional infectious and noninfectious hazards, rapidly identify and characterize new and emerging foodborne hazards, and investigate chronic, as well as acute, adverse health effects. Long term active surveillance and investigation could also be used to evaluate the effectiveness of food safety programs and the impact of regulatory change.

In summary, CDC's integral role in food safety issues is complementary to those of FDA, USDA, and state and local authorities. Meeting emerging foodborne disease problems in the 21st century will require enhanced programs to determine 1) who is at highest risk for foodborne infections and severe outcomes, 2) what are the important causes of foodborne disease, 3) what are the newly emerging foodborne disease threats, 4) what are the products, processes, and practices which contribute to foodborne infections, 5) what are the effective prevention and control strategies which will minimize contamination of food by disease-producing microorganisms, and 6) how effectively such strategies are implemented.

Thank you for the opportunity to discuss CDC's role in preventing foodborne disease. I will be happy to answer questions you or members of the Subcommittee may have.

Mr. TOWNS. Thank you very much, Dr. Blake.

Let me begin by saying, Ms. Sowerby, please accept my deepest sympathy on the loss of your son.

Ms. Kiner and Ms. Heersink, let me express my sorrow for the stress and strain your children and family have endured. You also have our sympathy.

The three of you have provided extremely compelling testimony of what is wrong with our system. The questions you raised demand answers, and rightfully so.

We also thank you for your courage in coming forth and sharing your painful experiences with the committee. Let me say to you we appreciate that as well.

We also thank you, Dr. Marcuse, and Dr. Blake, for your time today.

Ms. Heersink, your experience with E. coli happened in Alabama in 1992; is that correct?

Ms. HEERSINK. That is correct.

Mr. TOWNS. Ms. Kiner, your experience happened in Seattle in January 1993?

Ms. KINER. Yes, sir.

Mr. TOWNS. Ms. Sowerby, your experience happened in Michigan in June 1993; is that correct?

Ms. SOWERBY. Yes, sir.

Mr. TOWNS. Dr. Blake, how many cases and how many outbreaks of E. coli 0157:H7 occurred before the Seattle outbreak, and how many have occurred since? Do you know?

Dr. BLAKE. We do not have currently a specific reporting system for E. coli 0157:H7 in the United States. We are working with the States to begin such a system. We do try to keep track of outbreaks as they occur; and up through 1990, we have listed 12 outbreaks. These are the ones that we know about.

This year so far, there have been approximately 16 different clusters of E. coli 0157:H7. We cannot be sure these are outbreaks. They are clusters.

For example, there is a cluster right now in Texas. We do not yet know if that is an outbreak. Estimation of the size of the problem is really fraught with hazard because of the many differences in whether or not a child's stool is cultured, the ability of the laboratory to identify E. coli 0157:H7, whether or not the report gets to public health officials, and whether it ultimately reaches CDC. So the whole business of trying to estimate the size of the problem is very difficult.

Our best guess right now is that there are approximately 20,000 cases of E. coli 0157:H7 infections in the United States every year.

Mr. TOWNS. We want to be cautious. I think we should be; but it is safe to say the problem is pervasive and growing?

Dr. BLAKE. It does seem to be growing. This was first discovered in 1982 when two different outbreaks occurred, one in Michigan and one in Oregon, which were associated with the same fast-food hamburger chain.

At that point, we had never seen this disease before; and it was only with great difficulty that we ultimately discovered the organism that was causing it. In looking through over 3,000 strains of E. coli we collected over the years, we found only one example of

this particular organism, 0157:H7, that was in a woman in California who had the typical disease back in 1975.

Since then, this disease has become more and more apparent in the United States, in Canada, and in the United Kingdom. The three countries, in particular, have had a very serious problem with this disease.

We do not know why it is increasing the way it is. We suspect that it has something to do with this organism spreading from herd to herd of cows, getting into cows in some way. But we do not know how that is happening.

Mr. TOWNS. Dr. Marcuse, in your testimony, you indicated that we have known as early as 1987 about this problem, is that correct?

Dr. MARCUSE. That is correct.

Mr. TOWNS. If that is the case, we could have prevented the suffering of those 45 children your hospital treated if USDA had done something about the problem; is that correct?

Dr. MARCUSE. I think with good—with new knowledge and good enforcement, new techniques, good enforcement of those techniques, we can reduce the risk of this disease and of outbreaks. I don't think we can prevent all cases, but we can reduce the risks. There were opportunities to reduce this risk that have been missed.

Mr. TOWNS. Let me just ask—I see the red light is on, my time is up—let me ask you, Ms. Kiner, Ms. Sowerby, Ms. Heersink, if there was one thing we should ask USDA when they come before us on November 19, what should that be?

Ms. HEERSINK. I think that it would be wise to question the duality of the purpose of the USDA. On the one hand, it exists to promote agricultural products. That is very good. But is it fair then to ask the same agency to police the safety of those products? I think that if I had to say one thing that undermines even their most generous efforts, it has been this inherent conflict of interest.

Mr. TOWNS. Ms. Kiner.

Mr. SCHIFF. Mr. Chairman, I don't mean to interrupt the witness, but if I understand the Vice President's recommendations, it is along the same point the Vice President recommended in terms of transferring the responsibility from USDA to FDA. Excuse the interruption. I wanted to emphasize that point.

Ms. KINER. I think I would like to tell you a fact we haven't heard yet. Ed, I think, can confirm it for me. E. coli is the leading cause of renal failure in children in the United States. It is not some whimsey or some genetic breakdown in someone's heritage. This is the reason, bacteria is—why we have children—I am almost speechless, trying to get across to you how devastating this is on a broad spectrum, let alone Brianne's own story.

If I had my wish, it would be to have microbiologists involved in the testing, in the companies; and I was told by the head of FSIS, there was no such system for testing. It is not true. It is used in Europe. It is used in the seafood industry. Why can't we have it?

The American public will pay more for a safe product.

Mr. TOWNS. Ms. Sowerby.

Ms. SOWERBY. I think that is the point I wanted to make also, that I think we need to pursue the microbiological testing. My understanding is that it does exist, and I have been told by people

from the USDA that there is no such testing methods. I believe that there are. I think they need to pursue that strongly.

Mr. TOWNS. Thank you very much.

I yield now to the ranking member, Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

First, I want to say to the three parents, I want to share the sentiments expressed to you by the chairman. I don't think anyone, particularly a parent, in this room can be unmoved by the stories you went through.

Therefore, I don't mean to sound academic at this point, but obviously you have looked into this matter further from your own personal experiences. Therefore, I just wanted to ask a further question.

Ms. Sowerby, I think you talked about the failure of USDA to compel a certain labeling; but I am sorry, I didn't quite catch what that was. Could you go back over that for me, please? If I remember it?

Ms. SOWERBY. The labeling requirement?

Mr. SCHIFF. I thought you said there should have been a labeling of a health hazard that was either done later or not done. Do I remember that from your testimony?

I am sorry.

Ms. SOWERBY. The problem with the labeling, No. 1, it was not from the FSIS's hearts. It came about as a settlement of a lawsuit.

Mr. SCHIFF. What kind of labeling are you talking about?

Ms. SOWERBY. The labeling requirement that was supposed to have gone into effect on October 15, to be put on all meat products, about safe food handling; washing your hands, general information, cooking the meat thoroughly. I do want to point out that even though it does say "cook your meat thoroughly," what does thoroughly mean? My son ate "sloppy joes." That is a recipe where your meat is cooked thoroughly, you add a sauce, then you cook it again.

My son died. I had three other families in Michigan that phoned me after my son passed away that bought meat at the same grocery store.

They indicated to me they made spaghetti and tacos their meat was cooked. They had five members get sick also. They didn't require medical attention, but they did get sick.

What does "cook thoroughly" mean? The temperature requirement is not on the label. It just says "cook thoroughly." They are very general labels.

Mr. SCHIFF. That labeling is still not forthcoming?

Ms. SOWERBY. Sometimes not. There was a lawsuit filed by a food industry association to delay that.

Mr. SCHIFF. Let me turn over to Dr. Blake.

Dr. Blake, I wonder if you could expand on the idea, if I understood you correctly, that until fairly recently, this disease was not separately identified? In fact, now that you know about it, you have gone back and identified cases that were not identified previously; is that right?

Dr. BLAKE. Actually, when we went back as far as 1973, we were only able to identify one case; and the British and the Canadians likewise went back and looked through their E. coli strains and found only seven E. coli 0157:H7 infections between 1978 and 1982.

So that I suspect this is a organism that existed in very small numbers before 1981–1982; and since that time, the numbers have been growing very substantially.

Now, E. coli 0157:H7 is about the third most important cause of sporadic cases of foodborne disease in this country. It is clearly an exceedingly important organism. As far as we can tell, it is continuing to grow.

Mr. SCHIFF. Can you tell me when—I think you may have said it, but can you tell me when the bacteria was first identified, that is that you knew what you were dealing with? What year would that have been, approximately?

Dr. BLAKE. It was first identified as a organism that is associated with diarrhea, severe bloody diarrhea in 1982. We did have a organism stored away from 1975, from a woman in California who had a very similar disease.

There are many different E. coli. That is why this one is number "157." They are further subdivided by the "H." This is a "H7." It is not a "H2" or "H3." It is a "H7." There are an enormous number of different types of E. coli some of which cause particular diseases.

Mr. SCHIFF. You identify 1982 as essentially the year of identification?

Dr. BLAKE. Yes.

Mr. SCHIFF. When was the first incident that you might say was an outbreak of—one case is one case too many; but in a disease control sense, when was the first time you had a cluster?

Dr. BLAKE. The first single case was 1975. Then the first cluster was detected in 1982. We worked with the Oregon State Health Department on an outbreak there, which was tracked back to a restaurant that sold hamburgers. Ultimately we were able to show that the outbreak was caused by E. coli 0157:H7 in hamburgers. There were about 30 cases—actually 26 cases.

And then shortly thereafter, there was a——

Mr. SCHIFF. There were 30 cases in the cluster in 1982?

Dr. BLAKE. Right. Shortly thereafter, in the same year, there was another outbreak in Michigan associated with the same national fast-food hamburger chain. This was only the second time we had seen this disease; first, in Oregon, then in Michigan. This time again we found the same organism and suddenly it began to appear it might be something that was not just a one-time chance occurrence but something that might be a very major problem.

Mr. SCHIFF. Finally, if I understand correctly again, although you cannot at the present time offer an explanation, your professional opinion is that this bacteria is growing in numbers and therefore might be more liable to be in the meat supply of this country?

Dr. BLAKE. As far as we can tell, it does appear to be becoming more frequent and extensive. In the early years, it was largely clustered along the northern tier of States and was more common in Canada than in the United States. But right now, there is a pretty substantial problem in Texas and we have found individual cases here and there, throughout most of the States, so that it is no longer a problem that is confined to the northern States. It is a national problem.

Mr. SCHIFF. Although there is more I would like to ask, my time is up also.

I want to thank the witnesses.

Thank you, Mr. Chairman.

Mr. TOWNS. Thank you.

Thank you very much.

I want to thank all the witnesses, but let me say, based upon your vast experience, Dr. Blake, I don't want you to leave without asking another question, just for my information. How many pathogenic microorganisms threaten our food? Do you have any idea?

Dr. BLAKE. Well, there are a very large number. The big three are salmonella, which is mainly associated with poultry, eggs, and meat; campylobacter is about as important as salmonella, and that is associated principally with poultry; and then third is E. coli 157:H7 which is principally beef products.

It has been associated with apple cider and some other unusual vehicles, but it is mainly beef. Those are the big three.

There are many, many others. I couldn't give you the exact number, but I would say more than 50.

Mr. TOWNS. All right.

Thank you very much.

Let me also thank all the witnesses for your testimony. It has been extremely helpful.

Again, Ms. Sowerby, Ms. Kiner, and Ms. Heersink, you have my deepest sympathy. Thank you very much.

I would like to call our second panel, Mr. John Harman, from the General Accounting Office; Mr. Jim Ebbitt, from the USDA Office of Inspector General; and Dr. Catherine E. Woteki, from the National Academy of Sciences.

It is the custom of this committee that we swear our witnesses in.

[Witnesses sworn.]

Mr. TOWNS. Why don't you begin, Mr. Harman.

STATEMENT OF JOHN W. HARMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY EDWARD ZADJURA, ASSISTANT DIRECTOR

Mr. HARMAN. Mr. Chairman, members of the subcommittee, before I begin, I would like to introduce on the far left, Ed Zadjura, who has been responsible for our work in the food safety area for some years now, and has a great deal of experience.

There is very little I can add in terms of what has already been said here to demonstrate the need for revamping the Federal food safety system. This need is not a new one.

It has been the subject of over 60 reports, studies, and was actively debated in 1972 in response to a bill to create a consumer safety agency. Yet, over the past 11 years, there has been little or no basic change in the system, despite increased risks from microbial pathogens in meat and poultry products, in particular.

I think it is an understatement to say USDA simply has not responded to these increased risks despite being on notice since at least 1977 about the need to revise the system.

In summary, the current food safety system was not developed under a rational plan but has evolved over many years. It is outdated, inefficient, and does not effectively protect the public from major foodborne illnesses. Major fundamental changes are needed.

I would like to make four key points about the current system: First, current methods are inflexible and outdated. For example, meat and poultry inspection has changed little in 85 years and still relies on visual inspections of individual animal carcasses. Although this traditional method may identify some contamination, inspectors cannot see, smell or feel microbial pathogens which cause nearly all cases of foodborne illnesses.

Second, current oversight and enforcement activities are inconsistent. Firms that process food products that pose similar health risks to the public are inspected at widely differing frequencies depending on which agency and thus which regulatory approach governs them. Resource constraints rather than assessment of risk also influence oversight decisions.

Third, inspection resources are not efficiently used and inspections are sometimes duplicative. As a result, some foods and establishments may be receiving too much attention while others may not be receiving enough.

In addition, food establishments are sometimes inspected by more than one Federal agency because they process foods that are regulated under different Federal laws or because they participate in voluntary inspection or grading service programs.

Finally, the fourth point, the system is so complicated and diverse that many coordination agreements requiring agencies to notify each other of problems encountered during inspections are needed. Generally these have been ineffective in assuring that problems are corrected.

Many recommendations at improving the current system have been made over the years. However, these improvements have historically fallen short because of the inflexibility of the current system and because the agencies continue to operate under different food safety laws and appropriations. Our 1992 report called for a uniform risk-based inspection system that would address the problems I have just discussed and for a single food safety agency to implement and oversee that system.

This is not a new idea, as I mentioned earlier, and has recently been reinforced by the Vice President's NPR recommendations. We did not in our 1992 report try to answer such questions as to whether an entirely new agency should be created or whether USDA or HHS should house a consolidated food safety agency.

As we testified in 1972—as you see, Mr. Chairman, we go back a ways on this issue—what is important are certain principles: A clear commitment by the Federal Government to protect public health, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency.

We also testified that it is important for the food safety mission to be housed in an agency that is not charged with the responsibilities that might conflict or appear to conflict with the willingness to aggressively protect public health.

Since that time, this view has been reinforced by many groups. Transferring meat and poultry inspection activity to an agency independent of USDA, whether it is a newly created agency as proposed in 1972 or FDA as recommended by the NPR task force, would eliminate this apparent conflict of interest and help improve public confidence.

Transferring responsibilities to FDA would, we might point out, require a fundamental reengineering of that agency.

In any event, it is unlikely that basic long-term improvements in food safety will occur unless fundamental legislative and structural changes are made to the entire food safety system. In our view, creating a single food safety agency responsible for administering a uniform set of laws will provide the most effective structure to resolve longstanding problems to deal with emerging food safety issues and ensure a safe food supply.

Thank you, Mr. Chairman.

Mr. TOWNS. Thank you very much.

[The prepared statement of Mr. Harman follows:]

United States General Accounting Office

GAO

Testimony

Before the Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives

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FOOD SAFETY

A Unified, Risk-Based System Needed to Enhance Food Safety

Statement of John W. Harman,
Director, Food and Agriculture Issues,
Resources, Community, and Economic
Development Division

GAO/T-RCED-94-71

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here to discuss the current federal food safety system--particularly meat and poultry inspection--and whether this system should be revamped. Our testimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency Inspector Generals, and others.[1]

In summary, the current food safety system--which costs the federal treasury $1 billion annually--does not effectively protect the public from major foodborne illnesses. The current system was not developed under any rational plan but evolved over many years to address specific health threats from particular food products and has not responded to changing health risks. Efforts to address food safety continue to be hampered by inflexible and outdated inspection methods, inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts.

In hearings earlier this year on the highly publicized outbreak of illness in the Northwest caused by E. coli 0157:H7, a strain of deadly bacteria, we made several recommendations to improve the meat and poultry inspection program. However, we stated that the types of problems that plague the meat and poultry inspection program are systemic to the entire food safety system.

During the past 20 years other organizations--most recently, the Vice President's National Performance Review--have issued reports detailing similar problems and made numerous recommendations for change. While many of these recommendations have been agreed to and acted on, improvement efforts have fallen short largely because the agencies continue to operate under different regulatory approaches contained in their basic laws. Consequently, we believe it is unlikely that basic, long-term improvements in food safety will occur unless fundamental legislative and structural changes are made to the entire food safety system. In our view, creating a single food safety agency responsible for administering a uniform set of laws is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure a safe food supply.

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[1]In particular, Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992) and Food Safety: Building a Scientific, Risk-Based Meat and Poultry Inspection System (GAO/T-RCED-93-22, Mar. 16, 1993). See app. I for a listing of GAO and other reports issued since 1969 on the federal food safety inspection system.

BACKGROUND

The current federal food safety system consists of as many as 35 different laws and 12 agencies. Two agencies account for most federal food safety spending: the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), which is responsible for the safety of most foods, and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), which is responsible for the safety of meat and poultry products.

Despite this extensive effort, food safety remains a concern. Because many cases of foodborne illness go undiagnosed, the actual number of incidents is probably much higher than the conservative estimate of 6.5 million annually and, according to the Centers for Disease Control, may reach 80 million or more. While it is not possible to put a dollar figure on the pain and suffering caused by foodborne illness, efforts have been made to quantify the economic costs. For example, FDA and FSIS have estimated that the medical costs and lost productivity from foodborne illness total $17 billion to $23 billion per year.

CURRENT FEDERAL INSPECTION PROGRAM HAS SIGNIFICANT LIMITATIONS

The federal regulatory system did not develop under any rational plan. As the understanding of foodborne hazards grew, food safety concerns changed. Addressing one new worry after another, legislators amended old laws and enacted new ones. Programs emerged piecemeal, typically in response to particular health threats or economic crises. The laws not only assigned specific food commodities to particular agencies but also provided the agencies with different authorities and responsibilities, reflecting significantly different regulatory approaches.

As a result, inflexible and outdated inspection methods, inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts have hampered and continue to impede efforts to address public health concerns associated with existing and newly identified food safety risks. The system is not designed to identify or respond to these risks as demonstrated by the E. coli incident.

Inspection Methods Are Inflexible and Outdated

FSIS' meat and poultry inspection program depends on inflexible and outdated inspection methods. To keep meat and poultry from diseased animals off the market, the meat and poultry inspection acts require that at slaughter each individual animal

carcass be examined by a USDA inspector.[2] Under this traditional inspection, largely unchanged for 85 years, inspectors make judgments about disease conditions, abnormalities, and contamination in animals and carcasses on the basis of what they see, feel, and smell--a process known as organoleptic inspection. Although inspectors may identify some contamination using this traditional method, they cannot see, smell, or feel microbial pathogens, which cause nearly all cases of acute foodborne illness in the United States. Furthermore, neither FSIS nor the industry is currently required to routinely test for such pathogens on raw product.

With advances in animal and veterinary science, many infectious diseases have been controlled. Thus, the human health hazard posed by animal diseases has decreased while microbial hazards associated with the crowding of animals and other factors have grown. Nevertheless, FSIS, by law, must examine each individual carcass for signs of disease. These labor-intensive inspection procedures drain resources and limit the agency's ability to adjust inspection methods and frequencies to respond to changing health risks. To illustrate the impact on resources of inspecting every carcass, we calculated that over 1,800 inspectors were needed to visually examine the 6.8 billion poultry slaughtered in fiscal year 1992. Yet studies, including some conducted by FSIS, show that one-fourth or more of the poultry carcasses are contaminated with pathogens like salmonella that cannot be detected by such methods.

Oversight and Enforcement Authorities Are Inconsistent

Firms that process food products that pose similar health risks to the public are inspected at widely different frequencies, depending on which agency--and thus which regulatory approach--governs them. For example, firms that process meat and poultry (under FSIS' rules) are inspected at least daily, while firms that process seafood, which may be of similar risk, are inspected about once every 3 to 5 years (under FDA's rules).

Resource constraints, rather than an agreed assessment of risk, can also influence decisions on which agency will assume jurisdiction, thus precluding assignments of similar food products to one agency. For example, the decision for FSIS to have jurisdiction over open-face meat and poultry sandwiches made with one slice of bread, while FDA has jurisdiction over traditional meat and poultry sandwiches made with two slices of bread, was partly due to the resources that would be required for daily

[2]In fiscal year 1992, FSIS inspectors visually checked the carcasses of about 89.2 million swine, 30.8 million cattle, 5.1 million sheep and lambs, 1.8 million other livestock, and 6.8 billion chickens and other poultry.

inspection of all traditional meat and poultry sandwich plants by FSIS. According to FSIS officials, although the agency has over 7,000 inspectors, it lacked the resources to inspect all meat or poultry sandwich processors every day, so it decided to inspect the less common open-face sandwich, while leaving inspections of other sandwiches to FDA. As a result, processors of traditional sandwiches are unlikely to be inspected more often than once every 3 to 5 years by FDA, while processors of open-face meat and poultry sandwiches are inspected daily by FSIS. FDA and USDA officials said that there is no difference in the risk posed by these products.

Enforcement authorities granted to the agencies also differ. USDA's agencies have the authority to (1) require food processors to register so that they can be inspected, (2) presume that food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, and (4) temporarily detain any suspect foods. Conversely, FDA, without such authority, is often hindered in its ability to oversee food processors. In fact, because firms under its jurisdiction are not required to register, FDA is not aware of and does not oversee or inspect some domestic food processors. For example, in past reports we have noted that FDA was unaware of bottled water, deer, buffalo, and seafood processing plants involved in interstate commerce.

Inspection Resources Are Not Efficiently Used

Federal agencies are not using their inspection resources efficiently. Because the frequency of inspection is based on the agencies' regulatory approach, some foods and establishments may be receiving too much attention while others may not be receiving enough. What constitutes an appropriate level of inspection has been a long-standing issue in connection with FSIS' daily inspection requirement for meat and poultry processing plants. In addition, other inefficiencies result from duplicative inspections of the same firms by different federal agencies.

After slaughter, meat and poultry from government-inspected carcasses are inspected again if they are further processed. (Processing operations can include simple cutting and grinding, preparation of ready-to-eat products, or complex canning procedures.) FSIS has interpreted the federal inspection laws as requiring that all meat and poultry processing plants be visited at least once daily by a USDA inspector, who may spend from 15 minutes to several hours performing various inspection duties.

Our December 1977 report on FSIS' inspection program concluded that periodic unannounced inspections (referred to as discretionary inspection), instead of daily inspections, could be used to ensure the safety of meat and poultry, especially at plants with simple

operations and good compliance with regulations.[3] We recommended that the Secretary of Agriculture develop criteria for deciding the optimal frequency of inspection for individual processing plants.

In 1986, the Congress passed a law giving FSIS authority to test the concept of discretionary inspection over 6 years. However, when the law lapsed in 1992, FSIS had not implemented discretionary inspection except for conducting preliminary pilot tests and issuing a proposed regulation. Although the FSIS Administrator told us that the agency continues to support the concept of discretionary inspection, FSIS is not pursuing any legislative initiative to reimpose such authority.

The inspection of food establishments by more than one federal agency also contributes to inefficient use of inspection resources. Food establishments are sometimes inspected by more than one federal agency because they process foods that are regulated under different federal laws or because they participate in voluntary inspection or grading service programs. For example, some federal agencies, such as USDA's Agricultural Marketing Service and the Department of Commerce's National Marine Fisheries Service, operate as service agencies to industry by providing reimbursable grading services for meat, poultry, egg, dairy, and seafood products. These grading agencies usually perform inspections to ensure that the products are produced under sanitary conditions before receiving a federal grade. These inspections are in addition to the ones performed by the regulatory agency, usually FSIS or FDA. Although each federal agency has different responsibilities, their inspection tasks are basically the same. As a result, the inspections are often duplicative.

Coordination Is Ineffective

The federal agencies with different food safety responsibilities and authorities depend on coordination and cooperation to avoid duplication and/or gaps in coverage. However, coordination agreements, which require agencies to notify other responsible agencies of problems encountered during inspections, have not ensured that food safety problems are corrected. Unsanitary and other unsafe conditions have persisted in food processing plants because such notifications do not always take place or the problems referred to the responsible agency are not always promptly investigated. Effective use of the agreements has been hindered by a lack of agency resources to complete follow-up investigations once a referral has been made and an absence of adequate internal systems for assigning and tracking reported problems.

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[3]A Better Way for the Department of Agriculture to Inspect Meat and Poultry Processing Plants (CED-78-11, Dec. 9, 1977).

FEDERAL FOOD SAFETY SYSTEM NEEDS REVAMPING

In our 1992 report on the federal food safety system,[4] we made a series of recommendations to the department secretaries to improve coordination among their agencies, eliminate duplicative inspections, and correct other problems identified during our review. In their official responses to our report, the secretaries generally agreed with our recommendations and indicated that they had various initiatives planned or underway to correct the problems cited in our report. Nevertheless, our report also recognized that, although implementing these recommendations would help improve certain elements of the food safety inspection system, improvement efforts had historically fallen short because the agencies continued to operate under different food safety statutes and appropriations. We said that it was unlikely that major, long-term improvements will occur unless basic changes were made to the overall federal food safety and quality inspection system.

We concluded that a uniform, risk-based inspection system could help ensure a safe food supply, reduce or eliminate duplication, enhance coordination, and improve consumer confidence in the safety of the nation's food supply. We recommended that the Congress hold oversight hearings to evaluate options for revamping the food safety and quality system. We presented various options for achieving such a food safety system but we also pointed out that our analysis of the advantages and disadvantages of the options indicated that creating a single food safety agency was the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure the safety of our country's food supply.

In our view, making a single food safety agency responsible for administering a uniform set of federal laws would (1) increase efficiency by eliminating overlapping and duplicative efforts; (2) eliminate illogical and inconsistent treatment of food products that pose similar risks; (3) consolidate federal food safety appropriations, thus allowing the agency to target food safety resources where they are most needed; and (4) reduce administrative costs by eliminating redundant overhead and by realizing economies of scale.

CONSOLIDATION OF FOOD SAFETY AGENCIES IS A LONG-STANDING ISSUE

While our 1992 report supported the creation of a single food safety agency operating under a uniform set of food safety laws with a clear public health mission, adequate resources, and appropriate enforcement powers, we did not try to answer such questions as where in the federal bureaucracy such an agency should

[4]GAO/RCED-92-152.

be located, whether an entirely new agency should be created, or whether USDA or HHS should house a consolidated food safety agency. Nevertheless, with the Vice President's National Performance Review recommending, just 2 months ago, that all food safety functions be transferred to FDA, these organizational questions have become the center of debate.

Consolidating food safety activities is not a new concept. Such a concept was debated in 1972 in connection with a proposed bill to transfer FDA's responsibilities, including its food safety activities, to a new independent agency, called the Consumer Safety Agency. This new agency was to be responsible for, among other things, ensuring the safety of the nation's food supply, although meat and poultry inspection was to remain in USDA.

Our position on this issue has not changed from the one we voiced in 1972, when we testified that whether an independent single agency was preferable to a component of an existing department was a matter of judgment upon which opinions can differ.[5] We reasoned that what was important, no matter which setting was adopted, were certain principles: a clear commitment by the federal government to consumer protection, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency. We said that, although these principles can be influenced by organizational placement, they probably depend more on public and political concern for the importance of the mission.

We also believe, as we testified in 1972, that it is important for the food safety mission to be housed in an agency that is not charged with responsibilities that might conflict, or appear to conflict, with its willingness to aggressively administer its public health protection responsibilities. In 1972, we pointed out that, although the Secretary of Agriculture had established a separate agency dedicated to meat and poultry inspection and related consumer protection functions, the agency still remained in a department having a principal mission of serving the agriculture industry. We suggested that such activities be given to a new independent agency or an existing agency not in USDA in order to consolidate similar functions, allow flexibility in the use of resources, and eliminate overlapping activities.

Although in 1981 meat and poultry inspection responsibilities were transferred to the current Food Safety and Inspection Service, they remained, as they do today, in USDA, which has the dual responsibility of promoting agriculture and protecting the consumer. This dual responsibility is considered a conflict of

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[5]Hearings on the Consumer Safety Act of 1972 before the Subcommittee on Executive Reorganization and Government Research, Senate Committee on Government Operations, 1972.

interest by some groups, and tends to reduce public confidence in the federal government's ability to ensure the safety of the nation's food supply. For example, the Congressional Research Service, in a 1993 report on meat and poultry inspection, said that (1) the Government Accountability Project, an organization representing government and industry whistle-blowers, contended that FSIS' modernization initiatives were primarily to accommodate the industry's demands for faster production lines at the expense of public health and (2) the Safe Food Coalition, a coalition representing consumer, public health, whistle-blower, senior citizen, and labor interests, charged that USDA and FSIS consulted with industry before announcing the government's strategy for improving meat and poultry inspection but had not sought the views of consumer and labor groups.[6] Transferring meat and poultry inspection activities to an agency independent of USDA--whether it is a newly created agency as proposed in 1972 or FDA as recommended in the Vice President's National Performance Review report--would eliminate this apparent conflict of interest and help improve public confidence.

Regardless of where it is housed, an effective and logical food safety system needs to be based on a system of uniform laws, adequate enforcement powers, and inspection methods that take into consideration the risk posed by the product, process, and processor, along with the ultimate needs of the consumer. Unlike our current system, a flexible, risk-based system could also more effectively address changes in dietary needs and the public's concerns about the safety of the foods we eat.

CONCLUSIONS

The current food safety system does not effectively protect the public from foodborne illnesses. The nature of the threat to public health from food products has changed over time, but the food safety system has not adjusted accordingly. The adoption of a risk-based approach to inspections could lead to safer products and reduced costs as scarce resources are redirected from low-risk operations to high-risk areas that require greater coverage.

Past efforts to correct deficiencies of the federal food safety inspection system have fallen short because the responsible agencies have continued to operate under different food safety statutes and appropriation acts. To obtain a uniform, risk-based inspection system, basic changes need to be made to the current regulatory system. In our view, creating a single food safety agency is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure the safety of our country's food supply.

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[6]Meat and Poultry Inspection: Background and Current Issues (CRS-93-574 ENR, June 9, 1993)

Regardless of where the agency is located, there needs to be a clear commitment by the federal government to public health protection, adequate resources devoted to that purpose, and competent and aggressive administration of uniform food safety laws.

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Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions.

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ON THE FEDERAL FOOD SAFETY INSPECTION SYSTEM SINCE 1969

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Mr. TOWNS. Dr. Woteki.

STATEMENT OF CATHERINE E. WOTEKI, Ph.D., DIRECTOR, FOOD AND NUTRITION BOARD, INSTITUTE OF MEDICINE/NATIONAL ACADEMY OF SCIENCES

Dr. WOTEKI. Thank you and good morning. I am Catherine Woteki, director of the Food and Nutrition Board which is a division of the Institute of Medicine which is in turn part of the National Academy of Sciences.

The Department of Agriculture has called on the Food and Nutrition Board three times since 1983 to review its regulatory programs related to meat and poultry, to identify and to quantify the different risks that are posed to the public from eating these types of foods, and to recommend changes to the regulatory systems currently in place.

As part of that, we have also recommended specific types of research that need to be undertaken to increase the safety of these foods. My written testimony includes the recommendation of these three different reports along with their major findings.

In addition, in that written testimony, I make reference to a study the board has done also on seafood safety which you mentioned will be taken up in the future. I would be happy to provide you with further information about that report.

What I would like to do in my testimony today is to summarize the common findings and common recommendations for all of these studies that we have done.

In addition, I have provided to you and to members of the committee the summary of a report on emerging infections that the Institute completed very recently and in which we recommend how to deal with them and how to essentially improve our stance so that we can better confront these types of emerging diseases in the future.

I would request that my written testimony and the summary of this report on emerging infections be included as part of the record.

Mr. TOWNS. Without objection.

Dr. WOTEKI. As many of the others who have testified have already indicated, USDA's traditional meat and poultry inspection system has remained largely unchanged since the early 1900's. It consists primarily of inspectors examining specified organs of carcasses for visible lesions that may indicate the animal was diseased prior to butchering. Traditional inspection also involves checking for proper dressing of the carcass including removal of bruises or other blemishes.

The reports that I would like to summarize today have all reached the conclusion that this traditional meat and poultry inspection approach is inadequate and should not be used as the gold standard against which other proposed inspections or new technologies for food safety are judged.

Instead, the reports have recommended that the Federal Government should design its inspection programs to focus on contemporary public health issues in the emerging microbial pathogens and chemical contaminants. It should implement a trace-back system and a recall system from final sale to the producer for all animal food products that are destined to enter the human food sup-

ply. So it goes beyond the simple inspection at the point of slaughter or processing.

This is essential for generating data important to the prevention of human disease and to enable processors and the government to solve problems in the food chain. The Federal Government should insist that industry comply with its policies and procedures required to protect public health and foster public confidence in the safety of the food supply.

The second major conclusion is that while FSIS does test samples of meat and poultry products for microbial pathogens and chemical contaminants, its monitoring is not designed to prevent public disease or eliminate the risk to the public health.

A full-fledged inspection system designed to meet public health objective will require that FSIS develop scientifically sound, real-time sampling methods for detecting contaminated meat and poultry and again to implement a comprehensive system for identifying critical points in production and processing for reducing hazards.

The third conclusion is that in order to help ensure the success of new inspection procedures, the FSIS must work to improve communication with its inspectors. The skeptical opinion of the streamlined inspection system for cattle that was held by many inspectors should have convinced the agency that it is imperative to involve field employees in the development and implementation of these new procedures.

Lastly, I want to point out that meat contamination is not just a regulatory and inspection problem. The USDA and other Federal agencies that are concerned with public health and with education need to promote public education about food safety issues. No inspection system can guarantee a zero risk of meatborne disease or contamination.

The public, in our food preparation in cafeterias, restaurants, and also in the home must understand the crucial role of food handling, preparation, and serving methods in limiting foodborne disease. USDA's proposed labels are a step in the right direction but education is needed as well as information on labels.

Thank you for the opportunity to appear, and I would welcome questions.

Mr. TOWNS. Thank you very much, Dr. Woteki.

[The prepared statement of Dr. Woteki follows:]

The Scientific Basis for Meat and Poultry Inspection

Statement of

Catherine E. Woteki, Ph.D., R.D.
Director of the Food and Nutrition Board
Institute of Medicine/National Academy of Sciences

before the
Subcommittee on Human Resources and Intergovernmental Relations
Committee on Government Operations
U.S. House of Representatives

November 4, 1993

Good morning, Mr. Chairman and members of the Committee. I am Catherine Woteki, Director of the Food and Nutrition Board, a division of the Institute of Medicine of the National Academy of Sciences. The Food and Nutrition Board (FNB) was established in 1940 to address issues of national importance that pertain to the safety and adequacy of the nation's food supply. In its fifty years of existence, the Board has examined the science and made recommendations to improve food quality and safety, thereby contributing to improving public health and preventing diet-related diseases.

The Department of Agriculture (USDA) called on the FNB three times since 1983 to review the regulatory programs for meat and poultry, to identify and quantify various risks to the public from eating these foods, and to recommend changes to the regulatory systems currently in place and research to improve the safety of these foods. In my testimony today, I would like to review the major findings and recommendations from each report, and conclude with some comments about the reports' common themes. These common themes provide clear directions for reform of our current systems.

In addition, the Institute of Medicine studied emerging microbial threats to health determined what might be done to deal with them, and recommended how similar future threats might be confronted to lessen their impact on public health. Because many of the report's conclusions and recommendations are relevant to this hearing, I have appended a copy of the report's summary to my testimony.

Meat and Poultry Inspection

In 1983, the Food Safety and Inspection Service (FSIS) asked the FNB to address the following questions: Is the inspection system in place today adequate to meet new challenges? Are the initiatives taken by FSIS consistent with current concerns about public health? Can technological and chemical agents and advances in assessment of risks to human health be better applied to meat and poultry inspection? The committee organized to answer these questions was chaired by Robert H. Wasserman, and consisted of 12 members. Their answers to these questions were contained in a report issued in 1985 entitled: *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program.*

The committee's major conclusions were that the meat and poultry inspection program of the FSIS has in general been effective in ensuring that apparently healthy animals are slaughtered in clean and sanitary environments. FSIS has made progress in reducing risks to public health from conditions that can be observed during antemortem and postmortem inspection and that can be evaluated during processing. However, substantial challenges continue to confront the agency. Some aspects of the inspection system are poorly defined in terms of objectives relevant to public health. A risk-based allocation of resources, supported by modern technology and a systematic evaluation of the program, would be valuable.

The 1985 report found that new challenges were microbial and chemical contamination which the current postmortem inspection methods are not adequate to detect. The report concluded that the most effective way to prevent or minimize hazards presented by certain infectious agents and chemical residues in meat and poultry is to control these agents at their point of entry into the food chain, i.e. during the production phase on the farm and in feedlots. However, FSIS cannot exercise such control because it has no jurisdiction in those areas. Environmental contamination and improper use of feed additives fall within the purview of other government agencies such as the Food and Drug Administration and the Environmental Protection Agency. The problem is compounded by the absence of an effective national surveillance system for monitoring the disease status of food-animals and by an inadequate mechanism for tracing infected or contaminated animals back to their source.

The committee made a number of recommendations to FSIS to intensify its efforts to control and eliminate contamination with micro-organisms and chemicals that cause disease in humans. Such efforts should include evaluating rapid diagnostic procedures for detecting microorganisms and chemical residues, extending the principles of Hazard Analysis Critical Control Points (HACCP) into the daily operations of inspectors, and educating the general public, health care personnel, educators, and extension service workers in the safe handling of meat and poultry. To achieve the goal of installing a modern, technology-based inspection system, the committee recommended that FSIS develop a capability for conducting or contracting for scientific and technical research tailored to its needs, rather than depending on other USDA agencies.

Perhaps the committee's major contribution was to identify the characteristics of an optimal meat and poultry inspection program. Although composed 8 years ago, they are still timely. Many of these recommendations are under discussion within USDA to respond to the recent *E. coli* epidemic. The components of the system are listed below.

- A trace-back and recall system from final sale to producer for all animals and products destined to enter the human food supply. This is essential for the generation of data that are important to the prevention of disease in humans and that will enable processors and the government to solve problems in the food chain.

- Maximum use of plant personnel in process-by-process and day-to-day monitoring of critical control points, and FSIS oversight to ensure compliance.

- Use in all phases of inspection of a technically qualified team with up-to-date knowledge of veterinary medicine, food science, public health, food engineering, food technology, epidemiology, pathology, toxicology, microbiology, animal science, risk analysis, systems analysis, statistics, computer science, and economics. Similarly, managers should have

expertise in several relevant disciplines, including veterinary medicine, food science and technology, nutrition, public health, and public management. No one discipline should dominate management.

- An inspection system with different levels of intensity, reflecting the degree of public health risk at various stages in the process, the reliability of the monitoring system, the compliance history of the slaughterhouse or processing plant, and the special needs of the intended consumer (e.g., military personnel and schoolchildren).

- Development of a list of the diseases that can be identified by each step in the inspection procedure. This list should be used to determine whether the steps are useful for protecting human or animal health, useful for detecting aesthetically objectionable conditions, necessary to protect consumers against fraud, or able to provide other identifiable benefits.

- Random sampling of retained or condemned carcasses and parts of carcasses in order to develop definitive diagnoses. These diagnoses can be used to establish baseline data on etiologies associated with each condemnation category and to provide material for pathology correlation sessions as continuing education for in-plant veterinary medical officers.

- Rapid, inexpensive screening tests to detect a broad array of chemical compounds and biological products that may be hazardous to the consumer.

- An adequate sampling plan, designed to protect the consumer from exposure to chemicals that are not randomly distributed across the country.

- Emphasis on hazard analysis and critical control points (HACCP), limiting inspection where the historic yield of violations is low and where public health risks are negligible.

- Documented assurance, backed by substantial compliance enforcement, of the sanitary wholesomeness of all meat and poultry products.

- Enhanced enforcement capability to impose a broad range of penalties upon violators, including refusal to inspect and approve their products.

- Adequate resources to ensure continued improvement of the technological base of FSIS, including the development of new inspection technologies to reduce cross-contamination of carcasses and more comprehensive assessment of toxicological hazards.

- A mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology, pathology, and public health, combined with a recertification program.

- A substantial scientific and technical FSIS staff of respected scientists who play a substantial consultative role in the development of policy.

- The presence of standing advisory panels composed primarily of outside experts to provide consultation on both policy and practice regarding meat and poultry safety. Disciplines represented on these panels should include food science and technology, computer applications, microbiology, biostatistics, epidemiology, veterinary medicine, toxicology, systems analysis, animal health, economics, marketing, nutrition, and risk analysis. Again, no one discipline should dominate any panel. All major regulatory proposals should be reviewed by standing advisory panels prior to finalization.

- Strong liaison between FSIS, the Centers for Disease Control, the Food and Drug Administration, and relevant animal health agencies at the federal, state, and local levels to ensure that no hazards are overlooked.

- Substantial use of a rapid, timely, and flexible system (probably computer-based) to acquire, transfer, analyze, and make more widely available data related to inspection and to meat-borne hazards.

The committee encourages FSIS to compare its program with these criteria and to establish a schedule for incorporating missing components as soon as feasible.

Poultry Inspection

Responding to the 1985 report, the FSIS Administrator requested that the FNB conduct a follow-up study, specifically regarding poultry production, with the following objectives: development of a risk-assessment model applicable to the poultry production system and an explanation of how it might be used to evaluate poultry inspection procedures; a general evaluation of current FSIS poultry inspection programs using the conceptual framework of the model; and an assessment of the advantages of incorporating statistical sampling into poultry inspection procedures.

A committee, chaired by Dr. Joseph Rodricks and consisting of 6 members, issued its report *Poultry Inspection: The Basis for a Risk-Assessment Approach* in 1987. The committee concluded that a risk-assessment approach is needed to evaluate health hazards associated with poultry. The weight of the evidence reviewed suggested that the current program of visual inspection can not provide effective protection against the risks presented by microbial agents that are pathogenic to humans.

In its general recommendations, the committee strongly urged FSIS to adopt the well-established precepts of risk assessment as an integral part of its strategy to identify and manage public health risks associated with poultry. Rather than focusing on one procedure, such as bird-by-bird inspection, as the primary component of an inspection process, FSIS should direct its efforts toward the establishment of a comprehensive quality assurance program. Such a program would consist of several components, one of which might be organoleptic inspection. Finally, emphasis should be shifted from detection to prevention of problems at the earliest feasible stage in production to increase the effectiveness of poultry risk-management activities.

Cattle Inspection

FSIS acted on some of the recommendations in the 1985 report on meat and poultry inspection, and proposed the Streamlined Inspection System for Cattle (SIS-C) as the first step in modernizing slaughter inspection of fed cattle. FSIS again turned to the FNB to help to evaluate the effectiveness of the proposed SIS-C. While FSIS acknowledged that its current systems did not provide real-time monitoring for microbial or chemical hazards, the agency regarded SIS-C as an initial step towards those goals.

A 5-member committee, chaired by Dr. Robert Kahrs, prepared the report *Cattle Inspection*, which was released in 1990. To review the SIS-C, the committee made site visits to three pilot plants, interviewed 24 lay food inspectors, 6 inspectors in charge, 5 veterinarians, 5 supervising veterinarians, representatives of plant management, and plant quality control personnel. A public meeting was also held in which consumer advocates, food inspectors, former USDA scientists and inspectors, and representatives of the meat industry and national associations testified.

The SIS-C had been pilot tested in five meat packing plants. It was designed for use in plants that slaughter only "fed heifers and steers," that is, cattle fattened in feed lots specifically for slaughter. The primary difference between traditional inspections and SIS-C was that the streamlined system transferred several responsibilities from USDA inspectors to packing-plant employees. The philosophy behind the SIS-C, according to the committee, was to allow "industry to assume full responsibility for meat quality, permitting FSIS to concentrate on safety."

While recommending that the FSIS proceed with plans to implement, with some modifications, its proposed SIS-C, the committee repeated statements by the two previous expert panels that more fundamental changes are necessary to protect the public from health risks prevalent in modern production, marketing and food preparation systems. None of the inspection systems currently in use or being tested by FSIS is designed to detect or eliminate microbial or chemical hazards presented by meat products. Consequently, these inspections are more helpful in assuring quality aspects of meat products, such as palatability and appearance, rather than their safety. The committee recommended that quality control personnel be employed to implement a

partial quality control program that must be approved in advance and monitored by FSIS. Such programs identify critical points in the production process for monitoring and statistical sampling practices to evaluate the wholesomeness and acceptability of products throughout a work shift and over longer periods. The committee concluded that use of SIS-C without approved plant quality control programs may weaken protection of public safety over traditional inspection methods because of reduced oversight by government inspectors. Consequently, it recommended that such quality control programs be implemented for all plants that will use SIS-C and not just those operating at high speeds.

Seafood Safety

The FNB has also reviewed the safety of fish and shellfish in a report entitled *Seafood Safety* issued in 1991. While seafood is not the focus of this hearing, I mention it here because the study's findings are similar to those for meat and poultry. Most current health risks from eating seafood originate in the environment and should be dealt with by control of harvest or at the point of capture. With minor exceptions, risks cannot be identified by an organoleptic inspection system. Fish and shellfish pose some unique problems that set them apart from meat and poultry in that natural seafood toxins (e.g., ciguatera and scombroid toxins) are a major contributor to seafood-borne illnesses, and the industry for harvesting, handling, and distribution is more localized.

Conclusions

USDA's traditional meat and poultry inspection systems have remained largely unchanged from the early 1900's. They consist primarily of USDA inspectors' examining specified organs of carcasses for visible lesions that may indicate that the animal was diseased prior to butchering. Traditional inspection also involves checking for proper dressing of the carcass, including removal of bruises or other blemishes.

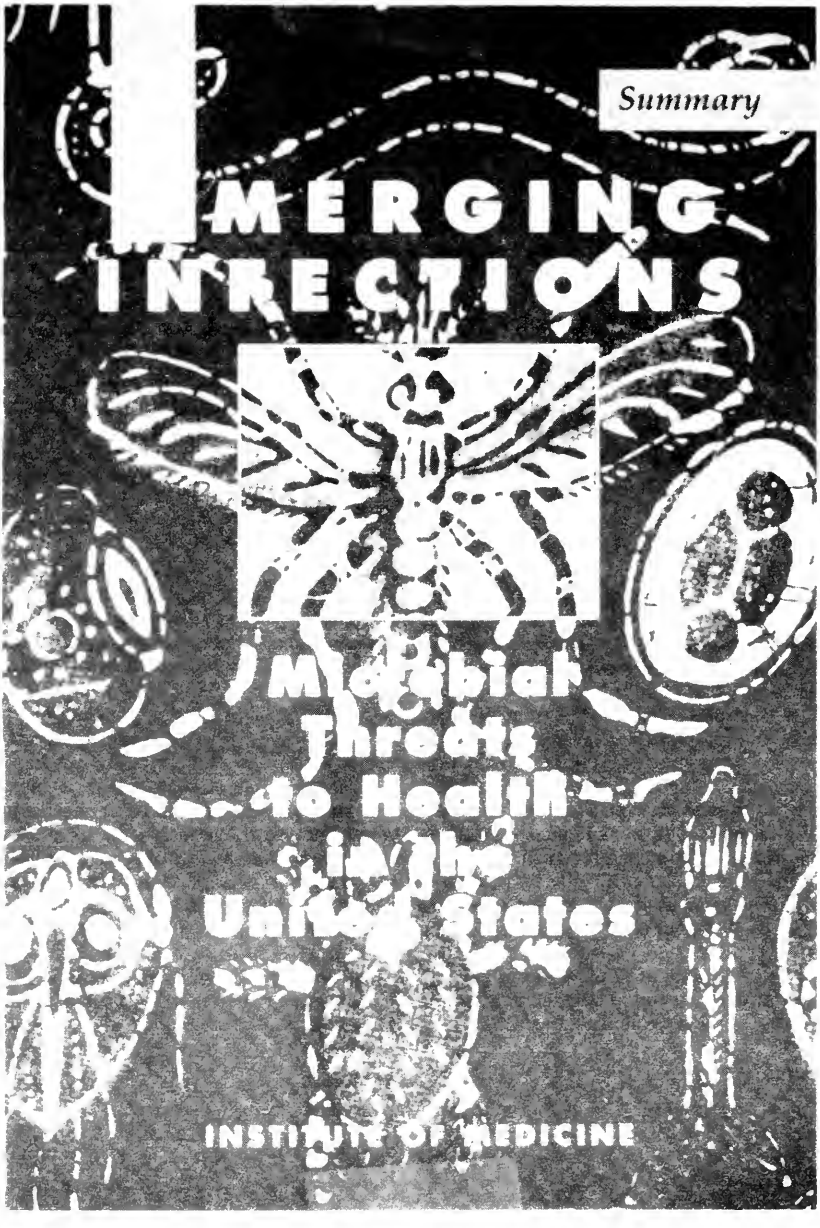
Traditional meat and poultry inspection should not be a gold standard against which other proposed inspections or new technologies for food safety are judged. Instead, the federal government should design its inspection programs to focus on contemporary public health issues, especially microbial pathogens and chemical contamination. It should implement a trace-back and recall system from final sale to producer for all animals and products destined to enter the human food supply. This is essential for generating data important to the prevention of human disease and to enable processors and the government to solve problems in the food chain. The federal government should insist that industry comply with policies and procedures required to protect public health and foster public confidence in the safety of the food supply.

While FSIS does test samples of meat and poultry products for microbial pathogens and chemical contamination, its monitoring is not designed to prevent public exposure or eliminate these risks to public health. A full-fledged inspection system

designed to meet public health objectives, will require that FSIS support research to develop scientifically sound real-time sample methods for detecting contaminated meat and poultry, implement a comprehensive system for identifying critical points in the production process for reducing hazards, and develop a practical system for tracing animals back to the source to locate and remove possible sources of chemical residues or contamination.

In order to help ensure the success of new inspection procedures, the FSIS must work to improve communication with its field inspectors. The skeptical opinion of the SIS-C held by some inspectors should have convinced the agency that it is imperative to involve its field employees in development and implementation of new procedures.

Moreover, USDA, other federal agencies and industry should promote public education about food safety issues. No inspection system, can guarantee zero risk of meat-borne disease or contamination. The public must understand the crucial role of food handling, preparation and serving methods in limiting food-borne disease.


Summary
EMERGING INFECTIONS
Microbial Threats to Health in the United States
INSTITUTE OF MEDICINE

Summary

EMERGING INFECTIONS

Microbial Threats to Health in the United States

Joshua Lederberg, Robert E. Shope,
and Stanley C. Oaks, Jr., *Editors*

Committee on Emerging Microbial Threats to Health
Division of Health Sciences Policy
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This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education. Dr. Kenneth I. Shine is president of the Institute of Medicine.

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Preface

As the human immunodeficiency virus (HIV) disease pandemic surely should have taught us, in the context of infectious diseases, there is nowhere in the world from which we are remote and no one from whom we are disconnected. Consequently, some infectious diseases that now affect people in other parts of the world represent potential threats to the United States because of global interdependence, modern transportation, trade, and changing social and cultural patterns.

The United States currently expends 14 percent of its gross national product on health; the vast majority of the money is spent on curative medicine to treat people who are already ill. The major premise of this report is that anticipation and prevention of infectious diseases are possible, necessary, and ultimately cost-effective.

In the battle against infectious disease, drugs, vaccines, and pesticides are important weapons. Because of the evolutionary potential of many microbes, however, the use of these weapons may inadvertently contribute to the selection of certain mutations, adaptations, and migrations that enable pathogens to proliferate or nonpathogens to acquire virulence. In those circumstances in which humankind has been successful in the battle against specific diseases, complacency (i.e., the assumption that we have conquered a disease and can thus shift our concern to other pressing problems) can also constitute a major threat to health. Such complacency can extend beyond those infectious diseases that have been successfully suppressed to embrace the concept that all infectious diseases are readily suppressed because of the advances of modern medicine. Shifting priorities, therefore, can allow for the reemergence, as well as the emergence, of diseases.

In May 1989, Rockefeller University, the National Institute of Allergy and Infectious Diseases, and the Fogarty International Center co-sponsored a conference on emerging viral agents. Although the conference focused on viruses, it spurred interest in the emergence and resurgence of *all* classes of infectious agents.

At the conference and in other forums, concern was expressed about the apparent complacency of the scientific and medical communities, the public, and the political leadership of the United States toward the danger of emerging infectious diseases and the potential for devastating epidemics. Recognizing these concerns, the Board on Health Sciences Policy of the Institute of Medicine (IOM) determined that the IOM could play a unique role by reviewing the relevant science, developing a research agenda, considering the implications for policy, and making specific recommendations for minimizing the public health impact of future emerging microbial threats. In mid-1989, a study proposal was developed and approved, and sponsors were secured. Thus, the 1989 conference served as an excellent prelude to the IOM study.

In February 1991, the IOM convened a 19-member multidisciplinary committee to conduct an 18-month study of emerging microbial threats to health. Committee expertise comprised the fields of epidemiology, virology, immunology, food safety microbiology, food toxicology, public health, molecular biology, cell biology, economics, microbial genetics, parasitology, infectious diseases, microbial pathogenesis, medical entomology and systematics, and bacterial physiology.

The charge to the Committee on Emerging Microbial Threats to Health was to identify significant emerging infectious diseases, determine what might be done to deal with them, and recommend how similar future threats might be confronted to lessen their impact on public health. The committee did not address biological warfare because this issue is already under study by another panel within the National Academy of Sciences.

The full committee held four meetings over the course of the study. At the first meeting, it was noted that a significant number of the members had ties to the biotechnology industry, which involved specific products such as diagnostic test kits and vaccines. Because the committee was not expected to make any disease- or product-specific recommendations, these ties were not considered to be conflicts of interest.

Also at the first meeting, the committee determined that, owing to the breadth of the topic, it would confine its work to emerging microbial threats to U.S. public health; it recognized, however, that even that topic could not be adequately addressed without considering emerging threats globally. The committee's recommendations thus target U.S. public health concerns, although they may have some relevance for the global population. The IOM published two earlier reports that bear on microbial threats outside the

United States: *The U.S. Capacity to Address Tropical Infectious Disease Problems* (1987) and *Malaria: Obstacles and Opportunities* (1991).

In addition to the meetings of the full committee, four task forces and a subcommittee met over the course of the study. The task forces provided additional information in four areas: bacteria, chlamydiae, and rickettsiae; viruses; protozoans, helminths, and fungi; and policy options. The subcommittee met to refine the committee's conclusions and recommendations.

For the purposes of this report, the committee makes an important distinction between infection and disease. Infection implies that an agent, such as a virus, has taken up residence in a host and is multiplying within it—perhaps with no outward signs or symptoms. In contrast, those who appear "sick" are said to have a "disease," and generally it is for these individuals that public concern is greatest. In fact, though, many more people usually are infected with the causative agent or exposed to the source of infection (such as an insect vector) than become ill. Controlling or limiting the disease depends in many cases on suppressing transmission. For example, although chronic carriers of hepatitis B virus or *Salmonella* bacteria may not be ill themselves, they are capable of transmitting infections to susceptible individuals and thus are a potential threat to public health.

Rather than organize the report around specific diseases, the committee decided to focus on factors that are implicated in the emergence of infectious diseases within the United States. The report begins with an executive summary, which reviews the main points of the committee's deliberations and presents its recommendations from Chapter 3. Chapter 1 provides background material for the general reader, lays out some of the reasons for optimism about the future, tempers that with information on some diseases that have recently emerged or that are emerging, and outlines the fundamental problems that must be addressed if we are to be prepared for the future. Chapter 2 defines "emerging microbial threats to health," identifies and discusses major factors in the emergence of such threats, and gives specific examples of situations in which these factors have been important to the emergence or reemergence of disease. The factors discussed are (1) human demographics and behavior, (2) technology and industry, (3) economic development and land use, (4) international travel and commerce, (5) microbial adaptation and change, and (6) breakdown of public health measures. Chapter 3 considers past and current efforts to address emerging threats in the context of recognition and intervention; it includes the committee's recommendations for approaching current and future emerging microbial threats. The report is written in large part as background for the general reader because the committee believes that the public needs to understand the importance of these threats.

It is this committee's considered opinion that the next major infectious agent to emerge as a threat to health in the United States may, like HIV,

be a pathogen that has not been previously recognized. Therefore, rather than attempt to list and discuss all organisms that might pose a future threat, this report uses examples to illustrate principles involved in the emergence of contemporary infectious diseases and the resurgence of old diseases. It is the committee's hope that lessons from the past will illuminate possible approaches to prevention and control of these diseases in the future.

Joshua Lederberg, Co-chair Robert E. Shope, Co-chair

Acknowledgments

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This study took place during a period of transition at the Institute of Medicine. Samuel Thier was president of the IOM at the initiation of the study. Following his move to Brandeis University in the fall of 1991, Stewart Bondurant became acting president. In January 1992, Kenneth Shine was designated president-elect; he assumed his full responsibilities in July 1992. The committee offers its sincere gratitude to these leaders and to Enriqueta Bond, the IOM executive officer, who provided guidance and advice during this critical period.

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Contents

Summary

Infectious agents—from bacteria and viruses, to protozoans, helminths, and fungi—have caused disease and death in human populations throughout history. Some of the most devastating "natural disasters" ever recorded have been caused by the uncontrolled spread of dangerous human pathogens. The plague epidemic of the Middle Ages, for example, was responsible for the deaths of a quarter of the population of Western Europe during a four-year period. More recently, in the first part of this century, pandemic influenza swept the world, killing 20 million people in less than a year's time, including 500,000 in the United States. Many experts believe that we are less vulnerable to these microscopic intruders now than at any time in the past. As the HIV pandemic has shown, however, serious microbial threats to health remain.

Infectious diseases constitute the major cause of death worldwide and will not be conquered during our lifetimes. With the application of new scientific knowledge, well-planned intervention strategies, adequate resources, and political will, many of these diseases may be prevented by immunization, contained by the use of drugs or vector-control methods, and, in very few cases, even eradicated—but the majority are likely to persevere. We can also be confident that new diseases will emerge, although it is impossible to predict their individual emergence in time and place. The committee believes that there are steps that can and must be taken to prepare for these eventualities. Its recommendations address both the recognition of and interventions against emerging infectious diseases.

Although there is good reason to be concerned about the potential health impacts of many well-known and newly discovered infectious agents, there is also reason for optimism. Tremendous strides have been and will con-

tinue to be made in the battle against infectious diseases. Advances in medical science and public health practices, in particular, have vastly improved our understanding of and ability to control many of these illnesses.

- The use of various public health and sanitation practices—for example, treatment and protection of drinking water supplies from human and other wastes—have dramatically reduced the incidence of some infectious diseases.
- The development of antimicrobial drugs, starting with the discovery of penicillin in 1929, has provided a host of useful compounds for combatting human infectious disease pathogens.
- The development and mass production of effective vaccines against such diseases as measles, pertussis, diphtheria, polio, and smallpox have protected large segments of the population from these and other potentially serious diseases.
- Proper storage, cleaning, and preparation of foods, in addition to the widespread pasteurization of milk, have reduced cases of bacterial food poisonings.

Perhaps the most heartening evidence of humankind's ability to triumph over infectious diseases is the eradication of smallpox, a viral infection that may have been responsible for the death of more people than any other acute infectious disease. Enabling factors in its eradication were the availability of an effective vaccine, a simple and effective means of administering it, and an extensive disease surveillance and containment effort. Current efforts to eliminate polio from the Western Hemisphere represent a similarly encouraging prospect.

Yet for the vast majority of infectious diseases, eradication is not a realistic objective. Thus, balanced against our history of progress is the reality of a world still very much at risk from microbial threats to health. Medical and epidemiological uncertainties hinder an exact count of the number of infectious diseases that afflict human populations at any point in time. There is little question, however, that we are aware of a greater number and variety of microbial pathogens than has ever been the case before.

During the past two decades, scientists have identified a host of apparently "new" infectious diseases, such as Lyme disease, that are affecting more and more people every year. Researchers are also discovering that some common illnesses with mysterious etiology may be partially the result of microbial infection. Such is the case for peptic ulcer and cervical cancer; researchers are also exploring possible infectious contributions to atherosclerosis, rheumatoid arthritis, and chronic fatigue syndrome.

The incidence of a number of familiar diseases is escalating, including some, such as malaria and tuberculosis, that were once under control in

many parts of the world. The waning effectiveness of certain approaches to disease control and treatment, changes in the way humans interact with the environment, and the enhanced susceptibility of certain individuals to infection all have contributed to the unwelcome reemergence of a number of microbial pathogens.

It is unrealistic to expect that humankind will win a complete victory over the multitude of existing microbial diseases or over all those that will emerge in the future. This will be true no matter how well stocked our armamentaria of drugs and vaccines, no matter how well planned our efforts to prevent and control epidemics, and no matter how advanced our basic science and clinical understanding of infectious diseases. Microbes are resilient and potentially dangerous foes.

With diligence and concerted action at many levels, however, the threats posed by emerging infectious diseases can be, if not eliminated, at least significantly moderated. For this goal to be achieved, four problems must be addressed. First, the general level of awareness of and concern about emerging disease agents needs to be raised. Second, existing domestic and international efforts at disease surveillance must be preserved and strengthened. Third, scientific gaps in knowledge about many infectious microbes must be addressed with both basic and applied research. Finally, the response to emerging disease threats, in this country and abroad, needs to be more aggressive and more timely.

FACTORS IN EMERGENCE

For the purposes of this study, emerging infections are those whose incidence in humans has increased within the past two decades or whose incidence threatens to increase in the near future. Emergence may be due to the spread of a new agent, to the recognition of an infection that has been present in the population but has gone undetected, or to the realization that an established disease has an infectious origin. Emergence may also be used to describe the reappearance (or "reemergence") of a known infection after a decline in incidence.

Considerable debate has centered on the relative importance of de novo evolution of infectious agents versus the transfer of existing agents to new host populations (so-called "microbial traffic"). Most emerging pathogens probably are not newly evolved but already exist in nature. Some may have existed in isolated human populations for some time; others, including many of the most novel emerging microbes, are well established in animals.

In the emergence of human infections, the significance of animal infections that are or may become transmissible to humans ("zoonoses") cannot be overstated. The introduction of animal pathogens into human populations is often the result of human activities, such as agriculture, that cause changes

in natural environments. These changes may place humans in contact with infected animals or with arthropod vectors of animal diseases.

Reemergence of "old" infectious agents can be the result of lapses in public health measures, changes in human behavior that increase person-to-person transmission of infectious agents, changes in food handling or eating habits, or changes in the way humans interact with their environment. As noted earlier, there are also a number of established diseases, such as cervical cancer, whose links to an infectious agent have only recently been discovered.

Emerging microbial threats to health can be classified by the type of agent involved, that is, as viral, bacterial, protozoal, helminthic, or fungal. For this report, however, the committee has chosen a different organizational framework: categorizing emerging infections according to factors related to their emergence. The committee used the following categories of factors to organize its discussion:

- Human demographics and behavior
- Technology and industry
- Economic development and land use
- International travel and commerce
- Microbial adaptation and change
- Breakdown of public health measures

This classification strategy draws attention to the specific forces that shape disease emergence. Of course, most human infections emerge because of a combination of factors. This is not surprising, given the often complex interactions of microbes, their human and animal hosts, and the environment. The committee's hope is that the use of this framework will permit better understanding and, perhaps, anticipation of the conditions that are likely to lead to the emergence of a microbial threat to human health. Once these steps are accomplished, efforts to modify or even eliminate such conditions can be undertaken.

Human Demographics and Behavior

In the complex set of interactions that result in disease emergence, the human element—population growth, density, and distribution; immunosuppression; and sexual activity and substance abuse—plays a critical role.

Until recently, most of the world's population lived in rural areas. Not only are more people living in urban areas, but the size and density of many cities are increasing. In many parts of the world, urban population growth has been accompanied by overcrowding, poor hygiene, inadequate sanitation, and unclean drinking water. Urban development, with its attendant

construction and infrastructure needs, has also caused ecological damage. These factors have created conditions under which certain disease-causing organisms and some of the vectors involved in their transmission have thrived and have made it more likely that people will acquire new pathogenic microbes.

Immunosuppression, which results from any number of factors (e.g., inherited disease, aging, HIV infection, radiation treatment), can lead to disease in an individual who otherwise would have been able to fend off illness. Human infections resulting from impaired immune defenses are known as opportunistic infections, since they are caused by microorganisms that "take advantage" of a person's weakened immune status. The incidence of opportunistic infections in the United States is likely to increase in the coming years, as the elderly population grows and cases of HIV disease continue to climb. New medical treatments and technologies—for example, therapy for collagen-vascular diseases like rheumatoid arthritis and vasculitis, cancer chemotherapy, and organ transplantation—have created other openings for opportunistic pathogens.

Human behavior—most notably sexual activity and more recently substance abuse—has played a key role in the emergence of infectious disease. Syphilis, a bacterial disease whose incidence declined markedly after the introduction of penicillin has undergone a resurgence in the United States. This increase has been attributed to, among other things, multiple-partner sex among crack cocaine addicts. The sex-for-drugs phenomenon is also playing a role in the spread of HIV disease, the most devastating sexually transmitted disease to emerge in modern times.

The role of sex for drugs in HIV transmission worldwide is small compared with that of noncommercial heterosexual transmission, transmission related to intravenous substance abuse, and transmission related to homosexual activity. The early spread of the disease, particularly in the United States and Europe, was related to behavior, namely, high-risk sexual practices of some male homosexuals. (In Africa, heterosexual transmission was and remains the primary mode of spread.) In the United States, intravenous substance abuse has become another major risk factor for HIV transmission. It now appears that HIV infection in this country is increasing most rapidly among non-substance-abusing heterosexuals.

Technology and Industry

For all of their benefits, technology and industry can, directly or indirectly, cause, or at least contribute to, the emergence of infectious diseases. Modern medicine has created situations that are ideally suited for the emergence of infectious agents. The food and agriculture industries continually work to prevent the introduction of pathogenic organisms into the U.S. food

supply, but they are not always successful. Waterborne pathogens are controlled by the careful treatment and disinfection of our drinking water, but breakdowns do occur, sometimes resulting in the spread of infectious disease.

Hospitals are fertile soil for emerging infections not only because such facilities harbor people with serious infections, but also because patients are often more susceptible to infection than the general population. Many standard hospital procedures facilitate acquisition of nosocomial (hospital-acquired) infections by inpatients. Conventional medical devices account for the greatest share of such diseases, of which urinary tract infections (especially from catheterization) are the most common; others include pneumonia, surgical wound infections, and bloodstream infections. Because of the widespread use of antibiotics, antimicrobial resistance has become an increasing problem in the hospital setting, with many nosocomial outbreaks caused by resistant organisms.

The potential for foods to be involved in the emergence or reemergence of microbial threats to human health is high, in large part because there are many points at which food safety can be compromised. The majority of diagnosed cases of food-borne disease of known etiology in the United States are bacterial in origin. In at least half of all outbreaks of food-borne illness, however, the exact cause is unknown; a percentage of these is almost certainly due to as yet unidentified pathogens.

Any change in the conditions or practices associated with the production of agricultural commodities can affect the safety of the food supply. For example, drought can make grains more susceptible to mycotoxin-producing fungi, which can threaten the health of both humans and livestock. Aquaculture and mariculture, two relatively recent offshoots of traditional agriculture, provide ideal conditions for the growth of *Aeromonas* species and other bacteria implicated as causes of nosocomial, wound, and water- and food-borne infections in humans. In addition, food processing and preservation technologies can have unexpected effects on the microbial safety of foods (e.g., the use of plastic overwraps for fresh mushrooms, which allowed the growth of a botulism-causing bacterium until holes were introduced in the plastic).

International trade has become so pervasive that it is virtually impossible to screen most of the food entering this country for known microbial hazards, let alone for new microbiological threats. Even when food is not directly involved, international commerce can affect food safety, as in a 1986 outbreak of shellfish-related paralytic poisonings in South Australia and Tasmania. The toxin-secreting microbes responsible for the outbreak, which normally are not found in that part of the world, are thought to have been transported in the bilge water of ocean-going freighters.

Water that is untreated or that does not receive adequate processing can transmit infectious agents, including bacteria, viruses, and protozoan parasites. The source for most of these pathogens is fecal contamination, occurring either before or after treatment. Fortunately, most water used in this country is effectively processed by municipal water treatment facilities, and waterborne disease outbreaks in the United States are uncommon. Water used for recreational purposes is occasionally the source of waterborne infectious disease outbreaks. Public health authorities are especially mindful of potential outbreaks following natural disasters, such as earthquakes and hurricanes, that can result in the contamination of municipal water supplies.

Economic Development and Land Use

Economic development and changes in land use patterns, because they often alter the environment, may bring humans into contact with potential new pathogens and lead to the emergence of new disease. For example, dam building may change the environment in which pathogens, vectors, and host animals coexist because it often involves the clearing, excavation, and flooding of vast areas of land.

Deforestation and subsequent reforestation may have similar effects. Early in the 1800s, the eastern United States was rendered virtually treeless when vast tracts of land were cleared to make way for agriculture. As the forests disappeared, the deer population became progressively smaller. During the mid-1800s, however, U.S. agriculture began a monumental transition westward to the Great Plains, and the resulting abandonment of farms soon caused vast portions of the East to be retaken by forests. Unlike the relatively open primeval forest, this new woodland was choked with undergrowth and contained no predators large enough to regulate deer populations. The deer began to proliferate, and people began to visit and live in forested, rural areas, a trend that continues today. The resulting proximity of humans, mice, deer, and ticks presented an ideal opening for the Lyme disease spirochete, which is transmitted by the bite of certain *Ixodes* ticks. Lyme disease is now the most common vector-borne disease in the United States.

Although it is a controversial issue, the potential effects of global warming on disease transmission must also be considered. This is particularly true for diseases caused by mosquito-borne viruses, since temperature increases in cooler climates may enlarge or shift areas suitable for mosquito breeding. Global warming-induced changes in levels of precipitation and humidity could also have profound effects on the range and survivability of both vectors and infectious agents.

International Travel and Commerce

Travel—specifically, the movement of people and microbes from one region to another—has always contributed to the emergence of infectious diseases. Syphilis, according to the view still most widely held, is believed to have been introduced into Europe by sailors returning from the New World, and European explorers are believed to have introduced smallpox to the Americas. Far more frequently, however, an introduced pathogen does not become well established. These so-called "transient" introductions, by infected foreign visitors or infected Americans returning from areas of the world in which particular infectious diseases are endemic, account for most cases of imported disease in this country. Most often, the diseases are recognized and treated before they can be transmitted to others.

Among the imported diseases that have been reported in the United States, the most currently troubling is malaria. Outbreaks of locally transmitted malaria, which appear to be associated with infected migrant workers, have occurred in southern California and Florida. These outbreaks have been small and so far relatively isolated, but the potential for explosive outbreaks and for the disease to become reestablished in the United States (where it was once endemic) exists, since competent mosquito vectors are present in abundance in some areas.

The international transportation of goods has indirectly led to the emergence of a number of infectious diseases. Most often, the culprits are infected animals in the cargo hold of a plane or ship, or bilge water contaminated with pathogenic microbes. The transportation of laboratory animals has also been known to play a role in disease emergence.

Microbial Adaptation and Change

To survive, most microbial species, whether pathogenic or not, must be well adapted to a particular ecological niche and must compete effectively with other microorganisms. Because of the relatively small amount of DNA or RNA, or both, that they carry, and their rapid growth rate and large populations, microbial pathogens can evolve very quickly. These evolutionary mechanisms allow them to adapt to new host cells or host species, produce "new" toxins, bypass or suppress inflammatory immune responses, and develop resistance to drugs and antibodies.

Viruses rely on genetic changes to achieve needed adaptability. However, these changes do not necessarily produce new pathogens capable of causing new diseases. RNA viruses are a case in point. On the one hand, their mutation rates are extraordinarily high (because, unlike DNA viruses, RNA viruses have no editing mechanisms for correcting errors made during replication). On the other hand, the clinical expressions of the diseases they

cause (such as poliomyelitis and measles) have remained constant for centuries. In other words, the mutations that so frequently occur in RNA viruses have tended *not* to result in new diseases, but are important in the perpetuation of infection.

Pathogenic bacteria exert their effects on humans by way of virulence factors. These factors vary from organism to organism and can often be transferred among receptive bacteria by bacteriophages and plasmids. Bacteria may possess more than one such factor, which include toxins, enzymes, adhesins, bacteriocins, hemolysins, and cell-invasion and drug-resistance factors. The virulence factors allow the bacteria to adapt and survive in the hostile environment of their hosts by helping to resist nonspecific host clearance mechanisms, acquire nutrients for growth, resist specific host immune mechanisms, and acquire a competitive advantage by inhibiting microbial competitors in the host.

The development of antimicrobial drug resistance in a known infectious agent, or of pesticide resistance in a known vector of a human pathogen, may be a greater threat to public health than the emergence of a new disease. No drug is universally effective against all organisms, and as a drug is used, resistant organisms often occur as spontaneous mutants, emerging from the initially susceptible population. This resistance most often occurs as the result of selective pressure exerted on the organism by the drug. In bacteria, resistance can also be transferred from one organism to another through the mechanism of mobile genetic elements such as plasmids. Treating resistant infections often requires the use of additional or more expensive and more toxic alternative drugs and can result in longer hospital stays; it can also involve a greater risk of death for the patient who harbors a resistant pathogen.

Resistance is also being seen in the treatment of viral diseases. Although some viral infections can be successfully treated with the few available antiviral medications, viral resistance to these drugs is occurring. In the emergence of antiviral resistance, selective pressure from the drugs again plays a role, selecting for resistant subpopulations or de novo mutants that are resistant. The frequency of emergence of such subpopulations, and the speed at which this occurs, varies according to particular virus-drug combinations; it is influenced as well by the type of infection and nature of the host.

High levels of pesticide use in agriculture have contributed to the development of resistance among insects, some of which may be vectors of disease. This is the case for DDT, which was once one of the most cost-effective vector-control tools available. Disease-carrying insects have also developed resistance to a number of chemical alternatives to DDT, and there is evidence that some insect vectors may develop resistance to the toxin of *Bacillus thuringiensis israeliensis*, one of the most promising and widely used microbial pesticides. Pesticide resistance and the legal restrictions placed on pesticide use increasingly hinder efforts to control disease vectors.

Breakdown of Public Health Measures

Beginning in the late 1970s and continuing into the 1980s, the attention given previously to acute infectious diseases by public health officials, physicians, and researchers began to wane, with a shift in focus to chronic, degenerative diseases. Much of the reason for this shift was the (mistaken) notion that microbial threats to health were a thing of the past. A byproduct of this shift in attention was complacency about the dangers posed by infectious diseases. Complacency—resulting from a misguided perception that the advanced U.S. health care system, with its array of medical technologies, is able to disarm almost any infectious disease threat—contributes to the breakdown of public health safeguards. In the United States, the recent reemergence of measles, a vaccine-preventable childhood illness, offers an example of the danger of poorly or incompletely carried out public health measures.

War and natural disasters, alone or in combination, have also led at times to the collapse of vital parts of the public health process and its infrastructure, opening the door for the emergence of potentially dangerous microbial pathogens. In fact, infectious diseases have produced higher hospital admission rates among U.S. troops and, until World War II, higher mortality rates than are produced by battle injuries.

ADDRESSING THE THREATS

The process by which an infectious disease emerges and is recognized and responded to can be complex. The relationships between and among emergence factors, recognition activities, and interventions are diagrammed in Figures 1 and 2.

Recognition

The key to recognizing new or emerging infectious diseases, and to tracking the prevalence of more established infectious diseases, is surveillance. A well-designed and well-implemented surveillance program can provide the means to detect unusual clusters of disease, document the geographic and demographic spread of an outbreak, and estimate the magnitude of the problem. It can also help describe the natural history of a disease, identify factors responsible for emergence, facilitate laboratory and epidemiological research, and assess the success of specific intervention efforts.

Unfortunately, there is insufficient appreciation of the value of comprehensive surveillance programs. Even among public health personnel, involvement in surveillance activities is often limited to collecting and transmitting disease-related data. This narrow view can interfere with an understanding of the objectives and significance of the overall effort.

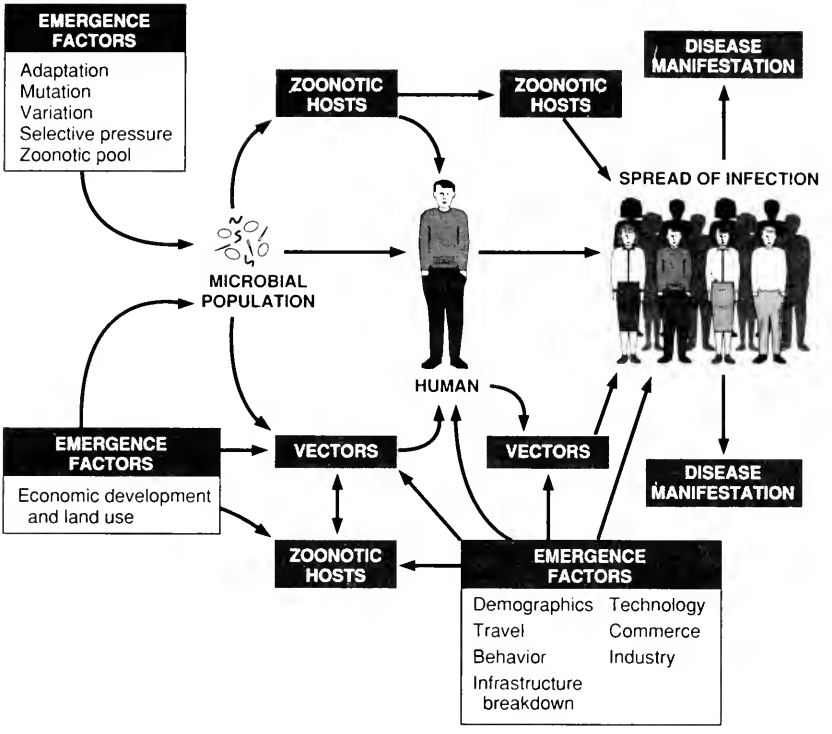

FIGURE 1 Schematic of infectious disease emergence.

Some health care and public health professionals are unfamiliar with surveillance methods because the topic is inadequately covered in medical schools and even in schools of public health. The result is often incomplete, underrepresentative, and untimely disease reporting. The importance of surveillance to the detection and control of emerging microbial threats cannot be overemphasized. Poor surveillance leaves policymakers and medical and public health professionals with no basis for developing and implementing policies for controlling the spread of infectious diseases. The committee does not know whether the impact of HIV disease could have been limited if there had been an effective global surveillance system in place in the 1960s or early 1970s. However, without such a system in place, we would have little chance for early detection of emerging diseases in the future.

Current U.S. disease surveillance efforts include both domestic and international components. Domestically, the bulk of federal disease reporting

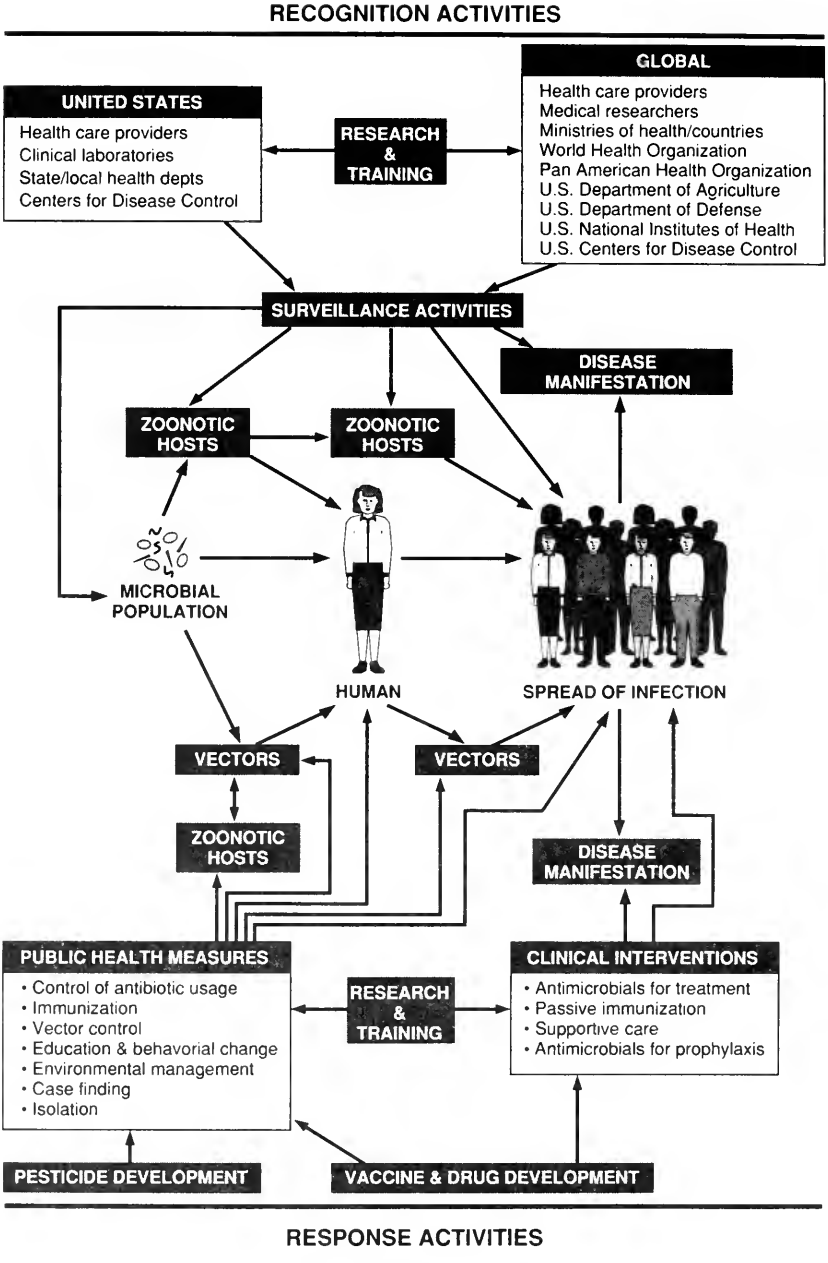

FIGURE 2 Recognition of and interventions for emerging diseases.

requirements (individual states also require reporting) are implemented through the National Notifiable Diseases Surveillance System, established in 1961. The list of notifiable diseases (currently numbering 49) is maintained and revised as needed by the Council of State and Territorial Epidemiologists in Collaboration with the Centers for Disease Control (CDC). The CDC also operates a domestic influenza surveillance program, which supplies epidemiological information to public health officials, physicians, the media, and the public.

Unfortunately, information on disease incidence is not always reported to local or state health departments. Clinical laboratories may not have sufficient resources for reporting or may decide that reporting is inconvenient. Similarly, some physicians may decide that reporting is too time-consuming, or they may be unaware of the requirement to report.

Outbreaks of any disease that is not on the CDC's current list of notifiable illnesses may go undetected altogether or may be detected only after an outbreak is well under way. In fact, except for food- and waterborne diseases, the United States has no comprehensive national system for detecting outbreaks of infectious disease. Emerging infectious diseases also are not reported through established surveillance activities.

The United States maintains a relatively substantial level of domestic infectious disease surveillance. Currently, however, there is little coordination among the various U.S. government agencies or between government agencies and private organizations involved in these efforts. The effectiveness of these efforts could be vastly improved by designating an agency or central coordinating body as a focus for such activities.

The committee recommends the development and implementation of strategies that would strengthen state and federal efforts in U.S. surveillance. Strategy development could be a function of the Centers for Disease Control (CDC). Alternatively, the strategy development and coordination functions could be assigned to a federal coordinating body (e.g., a subcommittee of the Federal Coordinating Council for Science, Engineering, and Technology's [FCCSET] Committee on Life Sciences and Health,[1] specifically constituted to address this issue. Implementa-

[1]The FCCSET is a federally appointed body of experts that serve on seven standing committees and act as a mechanism for coordinating science, engineering, technology, and related activities of the federal government that involve more than one agency. In addition to conducting cross-cutting analyses of programs and budgets, the various committees and their subcommittees (interagency working groups) examine wide-ranging topics with the goal of reaching consensus on fundamental assumptions and procedures that can guide the actions of the participating agencies in achieving their mission objectives more effectively.

tion of the strategies would be assigned to the appropriate federal agencies (e.g., CDC, National Institutes of Health, U.S. Department of Agriculture). Approaches for consideration could include simplifying current reporting forms and procedures, establishing a telephone hotline by which physicians could report unusual syndromes, and using electronic patient data collected by insurance companies to assist in infectious disease surveillance.

A second major domestic disease surveillance effort is the National Nosocomial Infectious Surveillance System (NNISS), which gathers data from approximately 120 sentinel hospitals and is operated by the CDC's Hospital Infection Program. Although nosocomial diseases constitute an important share of the burden of disease in this country, the system has several major limitations. For example, it cannot correct for differences among participating hospitals in diagnostic testing, surveillance intensity, and postdischarge surveillance. The requirement that NNISS member hospitals have at least 100 beds, and the fact that a relatively small sample of hospitals are included in the system, are also potential sources of bias. Current plans call for improvements in the dissemination of NNISS data, the inclusion of a surveillance component for immunosuppressed patients, and the addition of more sentinel hospitals, among other efforts.

The committee recommends that additional resources be allocated to the Centers for Disease Control to enhance the National Nosocomial Infections Surveillance System (NNISS) in the following ways:

1. Include data on antiviral drug resistance.

2. Include information on morbidity and mortality from nosocomial infections.

3. Increase the number of NNISS member hospitals.

4. Strive to make NNISS member hospitals more representative of all U.S. hospitals.

5. Evaluate the sensitivity and specificity of nosocomial infection surveillance activities performed in NNISS member hospitals.

6. Determine the reliability of antimicrobial susceptibility testing performed in NNISS member hospitals.

Considerable effort and resources are being expended on the various surveillance activities in which U.S. government agencies and the private sector participate. Much of this information, however, is not readily accessible. There is currently no single database from which a physician, researcher, health care worker, public health official, or other interested party can obtain information on disease incidence, antibiotic drug resistance, drug

and vaccine availability, or other information that might be relevant to infectious disease surveillance, prevention, treatment, and control.

The committee recommends that the U.S. Public Health Service develop a comprehensive, computerized infectious disease database. Such a database might consolidate information from more specialized sources, such as the National Nosocomial Infections Surveillance System (NNISS), the National Electronic Telecommunications System for Surveillance (NETSS), and the influenza surveillance system; it could also include additional information, such as vaccine and drug availability. As an alternative, expansion of currently available databases and provisions for easy access to these sources should be aggressively pursued. The implementation of such a program should also encompass expanded efforts to inform physicians, public health workers, clinical laboratories, and other relevant target groups of the availability of this information.

U.S.-supported overseas laboratories have played a historic role in the discovery and monitoring of infectious diseases. The United States and other nations first created these disease surveillance posts, many of them in tropical and subtropical countries, to protect the health of their citizens who were sent to settle or administer recently acquired territory. After World War II, there was a second blossoming of such activities. The Fogarty International Center was established, as were several overseas laboratories staffed by Department of Defense personnel. Privately funded activities, like those of the Rockefeller Foundation Virus Program, were important contributors to surveillance efforts.

Over the past two decades, a number of these facilities have been closed or are no longer operating with U.S. oversight. Nevertheless, although its efforts are substantially reduced from previous levels, the United States still maintains an international presence in infectious disease surveillance and research. Current efforts include the CDC's participation in the World Health Organization's (WHO) global influenza surveillance network and the Rockefeller Foundation's International Clinical Epidemiology Network. As with U.S. domestic surveillance efforts, the nation's international efforts, both governmental and private, remain largely uncoordinated.

The committee recommends that international infectious disease surveillance activities of U.S. government agencies be coordinated by the Centers for Disease Control (CDC). To provide the necessary link between U.S. domestic and international surveillance efforts, this body should be the same as that suggested earlier in the recommendation on domestic surveillance. Alternatively, a federal coordinating body (e.g., a

subcommittee of the Federal Coordinating Council for Science, Engineering, and Technology's [FCCSET] Committee on Life Sciences and Health, specifically constituted to address this issue) could be assigned the coordinating function. Implementation of surveillance activities, however, should remain with the appropriate federal agencies (e.g., the CDC, Department of Defense, National Institutes of Health, U.S. Department of Agriculture).

The efforts of multilateral international organizations, such as the WHO, are critical in coordinating infectious disease surveillance worldwide. The WHO is a focal point for surveillance data on a number of globally important infectious diseases. For example, under the International Health Regulations, all but four countries must report to the WHO within 24 hours all cases of cholera, plague, and yellow fever. (Despite the requirement to do so, some nations are reluctant to release surveillance data. Thus, some outbreaks of these diseases are never reported or are reported only retrospectively.) The WHO also operates a number of surveillance networks, composed of selected "collaborating centers" around the world that report and investigate outbreaks of specific diseases, such as influenza and HIV disease. The WHO is often involved in early investigative efforts related to newly emerging or reemerging infectious diseases (e.g., Ebola, Lassa, yellow, and dengue fevers).

Surveillance has played a key role in the efforts of the Pan American Health Organization (PAHO), starting in 1985, to interrupt the transmission of poliomyelitis in the Americas. Reporting of cases of acute flaccid paralysis is required of all participating countries. By the end of 1991, there were nearly 20,000 health units involved in the reporting system. In addition, eight diagnostic laboratories were established to conduct DNA-probe and polymerase chain reaction assays for poliovirus identification and characterization. This surveillance and laboratory network is being expanded to cover one or two other vaccine-preventable diseases. The network has already proved to be of great assistance in the detection and follow-up of the cholera epidemic that recently struck the Western Hemisphere.

Current U.S. and international surveillance efforts are useful for detecting known infectious and noninfectious diseases. They fall short, however, in their ability to detect emerging conditions. There has been no effort to develop and implement a global program of surveillance for emerging diseases or disease agents. One of the biggest potential barriers to the implementation of such a network is the difficulty of getting information to and receiving surveillance information from remote sites in many developing countries. A new satellite technology is currently being tested that may help resolve this problem.

The committee believes that an effective global surveillance network on emerging infectious diseases is an essential element in efforts to combat microbial threats and that it should have four basic components:

1. a mechanism for detecting (using clinical presentation as the criterion) clusters of new or unusual diseases or syndromes;
2. laboratories capable of identifying and characterizing infectious agents;
3. an information system to analyze reportable occurrences and to disseminate summary data; and
4. a response mechanism to provide feedback to reporting agencies and individuals and, if necessary, to mobilize investigative and control efforts of local and international agencies.

Such a network should also contain a number of other important elements, including locally staffed surveillance centers to promote regional self-reliance and train local personnel, links to academic centers and other regional facilities involved in basic research, a clinical arm for hospital-based surveillance and drug and vaccine trials, an effective specimen collection and transport system, and an active system of data analysis and dissemination, with feedback to those providing data. Models that may offer useful lessons for the design of such a system include the WHO's global influenza surveillance network and its collaborating centers for specific diseases, PAHO's polio eradication program, and previous initiatives, such as the WHO smallpox eradication campaign and the Rockefeller virus program.

The committee recommends that the United States take the lead in promoting the development and implementation of a comprehensive global infectious disease surveillance system. Such an effort could be undertaken through the U.S. representatives to the World Health Assembly. The system should capitalize on the lessons from past successes and on the infrastructure, momentum, and accomplishments of existing international networks, expanding and diversifying surveillance efforts to include known diseases as well as newly recognized ones. This effort, of necessity, will be multinational and will require regional and global coordination, advice, and resources from participating nations.

Intervention

The response to an emerging infectious agent or disease necessitates coordinated efforts by a variety of individuals, government agencies, and private organizations. The committee believes that the current U.S. capability for responding to microbial threats to health lacks organization and

resources. The recommendations in the subsections below address these deficiencies.

The U.S. Public Health System

In the United States, principal responsibility for protecting the public's health rests with the 50 state health departments, or their counterparts, and more than 3,000 local health agencies. At the federal level, the national focus for disease assessment is the CDC. A 1988 Institute of Medicine (IOM) report, *The Future of Public Health*, described the U.S. public health system as being in a state of disarray that resulted in "a hodgepodge of fractionated interests and programs, organizational turmoil among new agencies, and well-intended but unbalanced appropriations—without coherent direction by well-qualified professionals." It is the view of the committee that there has been little positive change in the state of U.S. public health since the release of the IOM report. The recent rapid increases in the incidence of measles and tuberculosis (TB) are evidence of these continuing problems.

Steps have now been taken to address inadequacies in measles vaccination and in the control of TB. These responses, however, are reactive, not proactive. It is the committee's belief that the prevention of infectious diseases must be stressed if the health of this nation's inhabitants is to be maintained or improved. Efforts directed at the recognition of and responses to emerging public health problems, particularly emerging infectious diseases, would help achieve this goal.

The problems of the U.S. public health system are drawing the attention of policymakers. Recently, the U.S. Public Health Service published a set of strategies for improving disease surveillance, epidemiology, and communication, three key areas of weakness cited in the 1988 IOM report. A number of the strategies are particularly relevant to the emerging disease issues addressed by the committee. If implemented, these suggested improvements will, in part, respond to recommendations made in this report.

Research and Training

Many of the factors that are responsible for, or that contribute to, the emergence of infectious diseases are now known. However, our understanding of these factors and of how they interact is incomplete. We are a considerable way from being able to develop strategies to anticipate the emergence of infectious diseases and to prevent them from becoming significant threats to health. The committee nevertheless sees this as a desirable long-term goal and concludes that research to achieve it should be strongly encouraged.

In July 1991, the National Institute of Allergy and Infectious Diseases (NIAID) convened a task force on microbiology and infectious diseases to identify promising research opportunities and recommend research strategies for future NIAID programs. The report from this group was released in January 1992. The committee has reviewed the NIAID report, believes that its study and the work of the task force are complementary, and fully supports the NIAID task force's conclusions and recommendations.

The committee recommends the expansion and coordination of National Institutes of Health-supported research on the agent, host, vector, and environmental factors that lead to emergence of infectious diseases. Such research should include studies on the agents and their biology, pathogenesis, and evolution; vectors and their control; vaccines; and antimicrobial drugs. One approach might be to issue a request for proposals (RFP) to address specific factors related to infectious disease emergence.

There are a number of programs that conduct research and training related to the epidemiology, prevention, and control of emerging microbial threats. Whether they involve U.S. or foreign scientists, have a broad or narrow focus, all of these programs contribute to the international capability to recognize and respond to emerging infectious diseases.

For example, the Rockefeller Foundation's International Clinical Epidemiology Network trains junior medical school faculty from developing countries in the discipline of epidemiology. After their training, these individuals return to their home countries, where they become part of a medical school-based training unit that helps evaluate the availability, effectiveness, and efficacy of health care. There are more than 27 such units in medical schools in Africa, Asia, India, and Latin America.

The NIAID supports two major programs with a focus on infectious and tropical diseases: the International Collaboration in Infectious Disease Research, which allows U.S. scientists to develop overseas work experience, and the Tropical Disease Research Unit program, which focuses on six diseases cited by the WHO as major health problems in the tropics. Recently, the NIAID consolidated these and several other efforts in international health under one new initiative, the International Centers for Tropical Disease Research. However, none of the NIAID programs specifically addresses emerging infectious diseases.

The CDC supports research and training in the area of infectious diseases through its National Center for Infectious Diseases (NCID). Earlier efforts by the agency, however, may also have valuable components that deserve revisiting. For example, from the mid-1960s to the early 1970s, the CDC administered an extramural program that awarded grants to academic

and other institutions for research in infectious disease prevention and control. The committee has concluded that the now defunct program filled a need for support in a critical area of research.

The committee recommends increased research on surveillance methods and applied control methods, on the costs and benefits of prevention, control, and treatment of infectious disease, and on the development and evaluation of diagnostic tests for infectious diseases. Reinstating and expanding (both in size and scope) the extramural grant program at the Centers for Disease Control, which ceased in 1973, would be one important step in this direction. Similarly, the FDA extramural grant program should be expanded to put greater emphasis on the development of improved laboratory tests for detecting emerging pathogens in food.

An adequate supply of well-trained, experienced epidemiologists is critical to the nation's surveillance efforts. CDC's Epidemic Intelligence Service (EIS) provides health professionals with two years of training and field experience in public health epidemiology. The program graduated 70 EIS officers in 1991. The EIS is the model for another evolving program, the joint CDC/WHO Field Epidemiology Training Program (FETP), which places field-oriented epidemiologists in countries that need to develop and implement disease prevention and control programs. Current and former EIS officers and FETP graduates are important sources of information on emerging diseases and constitute a personnel nucleus for a global surveillance network. The distribution of these epidemiologists, however, is restricted because of the limited number of program graduates each year.

The committee recommends the domestic and global expansion of the Center for Disease Control's (CDC) Epidemic Intelligence Service program and continued support for CDC's role in the Field Epidemiology Training Program.

The seven overseas medical research laboratories maintained by the DoD are the most broadly based international facilities of their kind supported by the United States. In addition to being well situated to recognize and study emerging disease threats, the facilities are valuable sites for testing new drugs and vaccines, since they are located in areas of the world in which the diseases of interest are endemic.

The committee recommends continued support—at a minimum, at their current level of funding—of Department of Defense overseas infectious disease laboratories.

In the area of training, previous studies have noted shortages of medical entomologists; clinical specialists trained in tropical disease diagnosis, prevention, and control; biomedical researchers; and public health specialists. The National Health Service Corps scholarship program, created in 1972, underwrites the costs of medical education in return for medical service in underserved areas of the United States. The committee is unaware of any similar program directed at individuals who wish to train for careers in public health and related disciplines. Such a program might attract those who otherwise might not consider careers in public health.

The committee recommends that Congress consider legislation to fund a program, modeled on the National Health Service Corps, for training in public health and related disciplines, such as epidemiology, infectious diseases, and medical entomology.

Vaccine and Drug Development

Vaccines and antimicrobial drugs have led to significant improvements in public health in the United States and much of the rest of the world during the latter half of this century. Despite this encouraging history, the committee is concerned that many of the vaccines and drugs available today are the same ones that have been used for decades. The committee believes that there is a need to review the present vaccine and drug armamentaria with a view toward improving availability and "surge" capacity, as well as safety and efficacy.

Advances in immunology, molecular biology, biochemistry, and materials sciences have stimulated major new initiatives in vaccine development. As a result, the generation of vaccines that will come into use in the next decade will be different from previous generations of vaccines. Some will contain more than one highly purified antigen and will rely on new delivery methods. The programmed-release biodegradable microsphere offers the possibility of single-dose regimens for parenteral vaccines. New oral vaccination methods will improve our ability to protect against enteric and respiratory agents. Research also centers on vaccines that use attenuated viruses and bacteria as vectors to introduce specific antigenic components of disease-causing microbes.

For all their potential, however, vaccines should not be viewed as magic bullets for defeating emerging microbial threats to health. The potential value of vaccination and the speed with which vaccines can be developed depend on many factors, such as the existing scientific knowledge of the agent (or a similar organism), its molecular biology, rate of transmission, pathogenesis, how the human immune system responds to natural infection, and the nature of protective immunity. Another important consideration

involves economic factors. Vaccine development may be impeded by the necessity for an extensive, up-front investment in research. Most vaccine manufacturers (and policymakers) are reluctant to make the required financial commitment since few vaccines are highly profitable and strict federal safety and efficacy requirements make the risk of failure a very real possibility. Vaccine developers must also take into account the extra costs that may arise from liability claims for injuries or deaths blamed on vaccines. This concern has forced a number of vaccine manufacturers out of the marketplace.

Industry might be encouraged to assume a greater role in vaccine development if asked to participate in a public/private sector collaboration, similar to NIH's National Cooperative Vaccine Development Groups, whose focus is HIV vaccines. Another alternative might be to offer industry various economic incentives, such as minimum guaranteed purchases, to conduct its own development work.

Given the various disincentives to vaccine development for more common pathogens, the development of vaccines for emerging microbes is even more problematic. There may be potentially catastrophic consequences if the development process is left entirely to free enterprise. A comprehensive strategy is urgently needed. To bring a new vaccine rapidly from the research laboratory into general use—a necessary criterion if one hopes to prevent or control an emerging infectious disease—will require an integrated national process that

- defines the need for a vaccine, its technical requirements, target populations, and delivery systems;
- ensures the purchase and use of the developed product through purchase guarantees and targeted immunization programs;
- relies as much as possible on the capability of private industry to manage the vaccine development process, through the use of contracted production, if necessary;
- utilizes the capacity of the NIAID to manage and support basic, applied, clinical, and field research, and of the CDC and academia to conduct field evaluations and develop implementation programs;
- is centrally coordinated to take maximal advantage of the capabilities of the public and private sectors; and
- is prepared for the possible rapid emergence of novel disease threats, such as occurred in the 1918-1919 influenza pandemic.

The committee recommends that the United States develop a means for generating stockpiles of selected vaccines and a "surge" capacity for vaccine development and production that could be mobilized to respond quickly to future infectious disease emergencies. Securing this capabil-

ity would require development of an integrated national process, as described above. The committee offers two options for implementation of this recommendation:

1. Develop an integrated management structure within the federal government and provide purchase guarantees, analogous to farm commodity loans, to vaccine manufacturers that are willing to develop the needed capacity.

2. Build government-supported research and development and production facilities, analogous to the National Cancer Institute's program for cancer therapeutics and the federal space, energy, and defense laboratories. The assigned mission of these new facilities would be vaccine development for future infectious disease contingencies.

The usefulness of antimicrobial drugs can be ensured only if they are used carefully and responsibly, and if new antimicrobials are continually being developed. The development of drug resistance by microorganisms, as well as the emergence of new organisms, will require replacement drugs to be in the pipeline even while existing drugs are still effective. The development of public/private sector alliances, along the lines of the National Cooperative Drug Development Groups at the NIH, may be desirable.

The committee recommends that clinicians, the research and development community, and the U.S. government (Centers for Disease Control, Food and Drug Administration, U.S. Department of Agriculture, and Department of Defense) introduce measures to ensure the availability and usefulness of antimicrobials and to prevent the emergence of resistance. These measures should include the education of health care personnel, veterinarians, and users in the agricultural sector regarding the importance of rational use of antimicrobials (to preclude their unwarranted use), a peer review process to monitor the use of antimicrobials, and surveillance of newly resistant organisms. Where required, there should be a commitment to publicly financed rapid development and expedited approval of new antimicrobials.

Vector Control

The United States and other developed countries have freed themselves to a remarkable degree from the burden of vector-borne diseases. A variety of methods of vector control have contributed to this success, including the spraying of chemical pesticides, application of biological control agents, destruction or treatment of larval development sites, and personal protection measures, such as applying repellents or sleeping under bednets.

For a disease agent that is known or suspected to be transmitted by an arthropod vector, efforts to control the vector can be vital for containing or halting an outbreak. This is true even for those vector-borne diseases, such as yellow fever or malaria, for which there is or may eventually be an effective vaccine. For most vector-borne infectious diseases, the onset of winter dampens transmission or can even eliminate the vector or infectious agent. The exception is pathogens that can survive in humans for long periods and produce chronic infection (e.g., malaria and typhus). A sudden drop in cases of an unidentified disease at the start of winter may be the first epidemiological evidence that the disease is vector borne.

North America has extensive vector-control resources. In addition to a massive mosquito-control program run by the state of California, there are some 1,000 additional ongoing regional and community vector-control and vector-surveillance efforts in the United States and Canada. In the United States, responsibility for organizing surveillance data and for investigating epidemics of emerging vector-borne disease, such as encephalitis, plague, and Lyme disease, rests with the CDC's Division of Vector-Borne Infectious Diseases in Fort Collins, Colorado.

Although many local and regional vector-control programs can effectively combat small and even medium-size outbreaks of vector-borne disease, they are not equipped to deal with outbreaks that are national in scope. For example, regional vector-control programs cannot declare a health emergency or bypass the many legal restrictions that now limit the use of certain pesticides that are potentially useful for vector control. That authority rests with health and environmental agencies at the state and federal levels. The lack of a sufficient stockpile of effective pesticides, which might be required in the event of a major epidemic, continues to be a serious problem.

The committee recommends that the Environmental Protection Agency develop and implement alternative, expedited procedures for the licensing of pesticides for use in vector-borne infectious disease emergencies. These procedures would include a means for stockpiling designated pesticides for such use.

A growing problem in vector control is the diminishing supply of effective pesticides. Federal and state regulations increasingly restrict the use and supply of such chemicals, largely as a result of concerns over human health or environmental safety. The 1972 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that all pesticides used in the United States be re-registered by 1997 (Public Law No. 92-516). Some pesticide manufacturers have chosen not to re-register their products because of the expense of gathering necessary safety data. As a result, a number of effective pesticides developed over the past 40 years are no longer available in

the United States. The Environmental Protection Agency (EPA) further restricts the use of pesticides through the Endangered Species Protection Plan, which prohibits the application of a wide range of pesticidal chemicals within the habitat of any endangered species. EPA has developed an emergency exemption procedure to allow pesticide use in restricted areas when the possibility of an outbreak of a vector-borne disease is great. The committee believes this procedure, which is extremely cumbersome and time-consuming, is essentially useless if followed as prescribed, since emergency approval of a pesticide would likely come after the critical period during which use of the pesticide could avert an outbreak.

As with vaccines, there is little economic incentive for firms to develop new pesticides for public health use, primarily because such use makes up a very small fraction of the total pesticide market. Pesticide development is now driven mainly by the demands of agriculture. Moreover, as pesticide development has become more specialized, there are fewer compounds available that have both agricultural and public health uses. The committee feels strongly that pesticide development for public health applications needs to be given some priority.

The use of dichlorodiphenyl trichloroethane (DDT), one of the most effective and economical pesticides ever developed, is banned in the United States for all but public health emergencies. A number of other pesticides, including aldrin, benzene hexachloride, chlordane, chlordimeform, diazinon, dieldrin, dinogeb, ethylene dibromide, andrin, and heptachlor have also been banned, suspended, or severely restricted. The American manufacturer of malathion, a pesticide used worldwide for both agricultural and public health purposes, has sold the rights to the compound to a Danish company, which may or may not re-register malathion in this country. Because malathion is an effective, relatively inexpensive, broad-spectrum pesticide, failure to re-register would be considerable cause for concern. Pyrethrum, a plant product that has been used successfully to control adult vectors and that is often in short supply, is currently being reviewed for its potential environmental and health hazards.

Agricultural applications account for about 75 percent of pesticide use in the United States. There are a number of approaches that can be used to delay or prevent the development of resistance. One, pesticide resistance management, rotates pesticidal chemicals, avoids applying sublethal doses, and uses biodegradable materials. More research is needed to hone the usefulness of this approach.

The committee recommends that additional priority and funding be afforded efforts to develop pesticides (and effective modes of application) and other measures for public health use in suppressing vector-borne infectious diseases.

Public Education and Behavioral Change

Public policy discussions and scientific efforts sometimes focus on vaccine and drug development to the exclusion of education and behavioral changes as means for preventing and controlling outbreaks of infectious disease. This is unfortunate, because often it is only by changing patterns of human activity—from travel, personal hygiene, and food handling, to sexual behavior and drug abuse—that the spread of disease can be halted.

Even when scientists and public health officials rely on education and encourage behavioral change to prevent or limit the spread of infectious disease, the public may not be convinced. Although scientists may see emerging microbes as a very real threat to public health, the average citizen may be unaware of the potential danger or consider those dangers to be less important than other health risks, like heart disease and cancer. In such instances, a carefully conceived media campaign may have a beneficial effect on behavior that affects disease transmission.

The committee recommends that the National Institutes of Health give increased priority to research on personal and community health practices relevant to disease transmission. Attention should also be focused on developing more effective ways to use education to enhance the health-promoting behavior of diverse target groups.

* * * * *

It is the committee's hope that this report will be an important first step in highlighting the growing problem of emerging microbial threats to health and focus attention on ways in which the United States and the global community can attempt to address such threats, now and in the future. The committee strongly believes that the best way to prepare for the future by developing and implementing preventive strategies that can meet the challenges offered by emerging and reemerging microbes. It is infinitely less costly, in every dimension, to attack an emerging disease at an early stage—and prevent its spread—than to rely on treatment to control the disease.

In some instances, what this report proposes will require additional funds. The committee recognizes and has wrestled with the discomforts that such recommendations can bring—for example, the awareness that there are other compelling needs that also justify—and require—increased expenditures. But everyone must realize and understand the potential magnitude of future epidemics in terms of human lives and monetary costs. The 1957 and 1968 influenza pandemics killed 90,000 people in the United States alone. The

direct cost of medical care was $3.4 billion[2] (more than three times the NIAID budget for fiscal year 1992), and the total economic burden was $26.8 billion[2]—almost three times the total NIH budget for fiscal year 1992. A more current example offers a similar lesson. The recent resurgence of TB (from 22,201 in 1985 to 26,283 cases in 1991, or 10.4 per 100,000 population), after a steady decline over the past several decades, will be costly. Every dollar spent on TB prevention and control in the United States produces an estimated $3 to $4 in savings; these savings increase dramatically when the cost of treating multidrug-resistant tuberculosis is factored in. We also have a recent example of what results when early prevention and control efforts are lacking. The costs of AIDS/HIV-disease—in human lives as well as dollars—have been staggering, and the end is not yet in sight. The objective in the future should be earlier detection of such emerging diseases, coupled with a timely effort to inform the population about how to lower their risk of becoming infected.

Obviously, even with unlimited funds, no guarantees can be offered that an emerging microbe will not spread disease and cause devastation. Instead, this committee cautiously advocates increased funding and proposes some more effective ways for organizations—both domestic and international, public and private—as well as individuals—both health professionals and the lay public—to work together and, in some cases, combine their resources. These efforts will help to ensure that we will be better prepared to respond to emerging infectious disease threats of the future.

[2] Study staff converted the figures to 1992 dollars using the NIH Biomedical Research and Development Price Index (BRDPI).

Mr. TOWNS. Mr. Ebbitt.

STATEMENT OF JAMES R. EBBITT, ASSISTANT INSPECTOR GENERAL FOR AUDIT, U.S. DEPARTMENT OF AGRICULTURE

Mr. EBBITT. Thank you, Mr. Chairman. I am Jim Ebbitt. With me this morning is Craig Beauchamp, Assistant Inspector General for Investigations at USDA. I am the Assistant Inspector General for Audit at the Department.

We are pleased to be here this morning to discuss specifically our review of the food safety inspection services regulation of the Cornhusker Packing Co. of Omaha, NE. We also wish to discuss the work we did with the agency as a result of that evaluation.

Secretary Espy asked us to review inspection activities at the Cornhusker Packing Co. in Nebraska after a network newscast depicted unsanitary conditions there. Secretary Espy had ordered the plant closed when conditions there became known.

We visited the plant in June 1993 accompanied by FSIS staff and reviewed operations, focusing on FSIS and plant management's control over inspection activities.

During our visits, we saw conditions similar to those shown on television and found that the plant had a history of sanitation problems—violations especially in the areas of rodent control and facility cleanliness and maintenance.

Because of the conditions we saw at Cornhusker, we immediately expanded our review to the five other plants under the same FSIS circuit supervisor as the Cornhusker plant. We did not find the same problems at those plants. Those plants were operating in accordance with regulations.

The problems at Cornhusker resulted from ineffective FSIS field supervision and uncooperative plant management which engaged only in short-term corrective actions when problems were noted. The basic problem in FSIS supervision at the plant was poor communication up and down the chain of command from the inspector in charge at the plant to the regional officials.

FSIS regional officials should have been aware of the problems but were not. An atmosphere of acceptance of poor sanitary conditions was the result.

When the conditions became known, FSIS stepped up its enforcement action against the plant and is holding plant managers to a schedule of corrective actions including eliminating harborage for rodents by replacing driveways to the carcass loading dock and sealing all doors to the plant; replacement and resealing of floors in the product areas; replacement of all windows on the kill floor and construction of an augur system to remove all inedible products from the kill floor without disruption or contamination of edible products.

On October 28, 1993, we returned to Cornhusker and found that substantial improvements to the plant facilities and equipment, as mentioned above, were either completed or well under way. We did find some continuing deficiencies in plant sanitary practices, but none which affected edible meat products. We did not observe any direct contamination of products.

Plant management continues to take corrective action, however, only as required by FSIS inspection staff. The plant has not devel-

oped effective plans for preventive maintenance for plant facilities and equipment and to provide assurance of proper sanitation practices throughout the plant.

In our opinion, the plant management's continued attitude of minimally meeting FSIS requirements, will require continuing intensive supervision from the inspection staff to assure the plant's meat products are wholesome.

Regarding FSIS oversight, we concluded that FSIS needs an overall inspection policy for plants that pose problems because of their age, their poor maintenance, and the type of cattle that they slaughter. With such a policy, FSIS could take proactive measures against plants whose managers permit multiple violations of product and facility standards.

To this end, we recommended that FSIS develop a problem plant profile and compile a list of plants that fit the profile for followup reviews. In response to this, and our other recommendations, FSIS officials advise us that our recommendations will be incorporated into their plans to achieve pathogen reduction and to improve oversight of plant inspection practices.

To improve oversight, FSIS officials asked us to help them reform their review program. We assigned an auditor and investigator to work with FSIS officials. This effort resulted in several initiatives to improve oversight activities. FSIS is already in the process of implementing a review and an assessment program that will better assess the causes of deficiencies during in-plant compliance reviews, incorporate scientific tests into reviews to supplement visual observations and interviews, and review information to provide an early warning of needed program improvements.

To conclude, Mr. Chairman, we are continuing to work with FSIS inspection staff. FSIS has included the Cornhusker plant in its microbiological baseline study and is currently taking samples there on a regular basis.

We will be happy to answer any questions.

[The prepared statement of Mr. Ebbitt follows:]

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

STATEMENT OF JAMES R. EBBITT
ASSISTANT INSPECTOR GENERAL FOR AUDIT
U.S. DEPARTMENT OF AGRICULTURE

BEFORE THE
SUBCOMMITTEE ON HUMAN RESOURCES
AND
INTERGOVERNMENTAL RELATIONS COMMITTEE
ON GOVERNMENT OPERATIONS

ON

Reinventing the Federal Food Safety and Quality System - U.S. Department of Agriculture's (USDA) Progress in Reforming Meat and Poultry Inspection

November 4, 1993
9:30 AM
Rayburn House Office Building, Rm 2154

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL

STATEMENT OF JAMES R. EBBITT
ASSISTANT INSPECTOR GENERAL FOR AUDIT
U.S. DEPARTMENT OF AGRICULTURE

BEFORE THE HOUSE SUBCOMMITTEE ON
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS
OF THE COMMITTEE ON GOVERNMENTAL OPERATIONS

ON THE EVALUATION OF THE
FOOD SAFETY AND INSPECTION SERVICES'
REGULATION OF CORNHUSKER PACKING COMPANY
OMAHA, NEBRASKA

NOVEMBER 4, 1993

THANK YOU MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE. I AM JAMES R. EBBITT, ASSISTANT INSPECTOR GENERAL FOR AUDIT, AND WITH ME THIS MORNING IS CRAIG L. BEAUCHAMP, ASSISTANT INSPECTOR GENERAL FOR INVESTIGATIONS.

WE ARE PLEASED TO APPEAR BEFORE YOU TODAY TO DISCUSS OUR REVIEW OF THE FOOD SAFETY AND INSPECTION SERVICE'S REGULATION OF THE CORNHUSKER PACKING COMPANY OF OMAHA, NEBRASKA. WE ALSO WISH TO DISCUSS THE WORK WE DID WITH THE AGENCY AS A RESULT OF THAT EVALUATION.

SECRETARY ESPY ASKED US TO REVIEW INSPECTION ACTIVITIES AT THE CORNHUSKER PACKING COMPANY IN NEBRASKA AFTER A NETWORK NEWSCAST DEPICTED UNSANITARY CONDITIONS THERE. SECRETARY ESPY HAD ORDERED THE PLANT CLOSED WHEN THE CONDITIONS THERE BECAME KNOWN. WE VISITED THE PLANT IN JUNE 1993, ACCOMPANIED BY FSIS STAFF AND REVIEWED OPERATIONS, FOCUSING ON FSIS AND PLANT MANAGEMENT'S CONTROL OVER INSPECTION ACTIVITIES. DURING OUR VISIT, WE SAW CONDITIONS SIMILAR TO THOSE SHOWN ON TELEVISION AND FOUND THAT THE PLANT HAD A HISTORY OF SANITATION

VIOLATIONS, ESPECIALLY IN THE AREAS OF RODENT CONTROL AND FACILITY CLEANLINESS AND MAINTENANCE.

BECAUSE OF THE CONDITIONS WE SAW AT CORNHUSKER, WE IMMEDIATELY EXPANDED OUR REVIEW TO THE FIVE OTHER PLANTS UNDER THE SAME FSIS CIRCUIT SUPERVISOR AS THE CORNHUSKER PLANT, BUT WE DID NOT FIND THE SAME PROBLEMS. THOSE PLANTS WERE OPERATING IN ACCORDANCE WITH REGULATIONS.

THE PROBLEMS AT CORNHUSKER RESULTED FROM INEFFECTIVE FSIS FIELD SUPERVISION AND UNCOOPERATIVE PLANT MANAGEMENT, WHO ENGAGED ONLY IN SHORT-TERM CORRECTIVE ACTIONS WHEN PROBLEMS WERE NOTED. THE BASIC PROBLEM IN FSIS SUPERVISION AT THE PLANT WAS POOR COMMUNICATION UP AND DOWN THE CHAIN OF COMMAND, FROM THE INSPECTOR-IN-CHARGE AT THE PLANT TO THE REGIONAL OFFICIALS. FSIS REGIONAL OFFICIALS SHOULD HAVE BEEN AWARE OF THE PROBLEMS BUT WERE NOT. AN ATMOSPHERE OF ACCEPTANCE OF POOR SANITARY CONDITIONS WAS THE RESULT.

WHEN THE CONDITIONS BECOME KNOWN, FSIS STEPPED UP ITS ENFORCEMENT ACTION AGAINST THE PLANT AND IS HOLDING PLANT MANAGERS TO A SCHEDULE OF CORRECTIVE ACTIONS, INCLUDING:

- ELIMINATING HARBORAGE FOR RODENTS BY REPLACING THE DRIVEWAYS TO THE CARCASS LOADING DOCK AND SEALING ALL DOORS TO THE PLANT.

- REPLACEMENT AND RESEALING OF FLOORS IN THE PRODUCT AREA;

- REPLACEMENT OF ALL WINDOWS ON THE KILL FLOOR;

- CONSTRUCTION OF AN AUGER SYSTEM TO REMOVE ALL INEDIBLE PRODUCTS FROM THE KILL FLOOR WITHOUT DISRUPTION OR CONTAMINATION OF EDIBLE PRODUCTS;

ON OCTOBER 28, 1993, WE RETURNED TO THE PLANT AND FOUND THAT SUBSTANTIAL IMPROVEMENTS TO THE PLANT FACILITIES AND EQUIPMENT, AS MENTIONED ABOVE, WERE EITHER COMPLETED OR WELL UNDERWAY. WE DID FIND SOME CONTINUING DEFICIENCIES IN PLANT SANITARY PRACTICES, BUT NONE WHICH AFFECTED EDIBLE MEAT PRODUCTS. WE DID NOT OBSERVE ANY DIRECT CONTAMINATION OF PRODUCTS. PLANT MANAGEMENT CONTINUES TO TAKE CORRECTIVE ACTIONS ONLY AS REQUIRED BY THE FSIS INSPECTION STAFF. THE PLANT HAS NOT DEVELOPED EFFECTIVE PLANS FOR PREVENTIVE MAINTENANCE FOR PLANT FACILITIES AND EQUIPMENT AND TO PROVIDE ASSURANCE OF PROPER SANITATION PRACTICES THROUGHOUT THE PLANT. IN OUR OPINION, THE PLANT MANAGEMENT'S CONTINUED ATTITUDE OF MINIMALLY MEETING FSIS REQUIREMENTS WILL REQUIRE CONTINUING INTENSIVE SUPERVISION FROM THE INSPECTION STAFF TO ASSURE THE PLANT'S MEAT PRODUCTS ARE SAFE AND WHOLESOME.

REGARDING FSIS OVERSIGHT, WE CONCLUDED THAT FSIS NEEDS AN OVERALL INSPECTION POLICY FOR PLANTS THAT POSE PROBLEMS BECAUSE OF THEIR AGE, THEIR POOR MAINTENANCE, AND THE TYPE OF CATTLE THEY SLAUGHTER. WITH SUCH A POLICY, FSIS COULD TAKE PROACTIVE MEASURES AGAINST PLANTS WHOSE MANAGERS PERMIT MULTIPLE VIOLATIONS OF PRODUCT AND FACILITY STANDARDS.

TO THIS END, WE RECOMMENDED THAT FSIS DEVELOP A PROBLEM PLANT PROFILE AND COMPILE A LIST OF PLANTS THAT FIT THE PROFILE FOR FOLLOWUP REVIEWS. IN RESPONSE TO THIS AND OUR OTHER RECOMMENDATIONS, FSIS OFFICIALS ADVISED THAT OUR RECOMMENDATIONS WILL BE INCORPORATED INTO THEIR PLANS TO ACHIEVE PATHOGEN REDUCTION AND TO

IMPROVE OVERSIGHT OF PLANT INSPECTION PRACTICES. TO IMPROVE OVERSIGHT, FSIS OFFICIALS ASKED US TO HELP THEM REFORM THEIR REVIEW PROGRAM.

WE ASSIGNED AN AUDITOR AND INVESTIGATOR TO WORK WITH FSIS OFFICIALS. THIS EFFORT RESULTED IN SEVERAL INITIATIVES TO IMPROVE THEIR OVERSIGHT ACTIVITIES. FSIS IS ALREADY IN THE PROCESS OF IMPLEMENTING A REVIEW AND ASSESSMENT PROGRAM THAT WILL:

- BETTER ASSESS THE CAUSES OF DEFICIENCIES DURING THEIR IN-PLANT COMPLIANCE REVIEWS.

- INCORPORATE SCIENTIFIC TESTS INTO REVIEWS TO SUPPLEMENT VISUAL OBSERVATIONS AND INTERVIEWS.

- USE REVIEW INFORMATION TO PROVIDE AN EARLY WARNING OF NEEDED PROGRAM IMPROVEMENTS.

AS A FIRST STEP TOWARD DEVELOPING A PROFILE SYSTEM ALONG THE LINES WE RECOMMENDED, FSIS HAS CANVASED INSPECTION AND OTHER STAFF TO COMPILE A LIST OF PLANTS WHICH HAVE A NONCOMPLIANT HISTORY WITH INSPECTION REQUIREMENTS. FSIS WILL USE THIS LIST TO MAKE UNANNOUNCED VISITS TO DETERMINE WHETHER THE PLANTS ARE COMPLYING WITH REQUIREMENTS. THEY ARE ALSO SELECTING A RANDOM SAMPLE OF PLANTS TO SERVE AS A CONTROL GROUP FOR FIELD REVIEWS. A COMPARATIVE STUDY OF THE DIFFERENCES BETWEEN THESE TWO GROUPS WILL BE USED TO DEVELOP A SYSTEM THAT CAN BE APPLIED TO ALL FSIS INSPECTED FACILITIES TO IDENTIFY POTENTIAL PROBLEM PLANTS.

OUR OTHER RECOMMENDATIONS INCLUDED MICROBIAL TESTING AT CORNHUSKER, IMPROVED COMMUNICATION, UP AND DOWN THE FSIS CHAIN OF COMMAND, AND THE TRACKING AND INVESTIGATION OF COMPLAINTS OUTSIDE THE NORMAL CHAIN OF COMMAND WHICH ALLEGE PROBLEMS IN ANY PLANT.

FSIS HAS INCLUDED CORNHUSKER IN ITS MICROBIOLOGICAL BASELINE STUDY AND IS CURRENTLY TAKING SAMPLES THERE ON A REGULAR BASIS. STEPS HAVE ALSO BEEN TAKEN TO IMPROVE COMMUNICATION BY ENHANCING REQUIREMENTS FOR REGIONAL, AREA, AND CIRCUIT LEVELS TO MORE CLOSELY MONITOR PLANT COMPLIANCE AND INSPECTOR PERFORMANCE THROUGH ONSITE REVIEWS.

FINALLY, THE NEW FSIS REVIEW AND ASSESSMENT OFFICE HAS ESTABLISHED A COMPLAINT TRACKING SYSTEM TO IDENTIFY AND TRACK ESTABLISHMENT SPECIFIC EMPLOYEE COMPLAINTS CONCERNING HEALTH ISSUES AND SYSTEM INTEGRITY. COMPLAINTS WILL BE TRACKED UNTIL RESOLVED, AND ALSO BE ANALYZED AS TO TYPES AND SOURCES OF COMPLAINTS.

IN ADDITION TO THE ACTIVITIES I HAVE BEEN DESCRIBING, WE HAVE SEVERAL OTHER AUDITS THAT ARE PLANNED THIS FISCAL YEAR TO ENSURE THAT EXISTING INSPECTION ACTIVITIES ARE BEING CONDUCTED EFFECTIVELY. WE ARE ALSO REVIEWING THE ACTIVITIES OF STATE OPERATED MEAT INSPECTION PROGRAMS.

THIS CONCLUDES MY STATEMENT MR. CHAIRMAN. I WILL BE HAPPY TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

Mr. TOWNS. Thank you very much. We appreciate your testimony.

May I just add that we have been joined by Congressman Payne from New Jersey and Congressman Mica from Florida. We will recognize them later on.

Mr. Harman, in 1972, GAO concluded that USDA's dual role in agriculture and protecting consumers appeared to be a conflict. Has anything changed or does GAO still believe that USDA's dual role is a conflict?

Mr. HARMAN. There have been changes particularly in the early 1980's when USDA tried to separate out and create an FSIS, a couple efforts to do it within the Department. But nonetheless, the situation that existed back when we made that 1972 testimony still exists today.

In addition to ensuring safe meat and poultry, the Department of Agriculture has as one of its major, if not basic, functions promotion of agriculture. We have come to believe that these functions can conflict and this problem has hindered their ability to implement some of these changes that have needed to be made. They run into a lot of problems with consumer groups, with their unions to some extent because of this perception, whether it is real or perceived, of a conflict of interest.

I would say that is not the primary reason that we are calling for a single food safety agency but it is certainly a major factor.

Mr. TOWNS. Your written statement concludes that the current food safety system does not effectively protect the public from foodborne illnesses. Does this mean the food supply is not as safe as people think it is?

Mr. HARMAN. Not from microbial pathogens. I think you have heard a lot of that this morning and it is just not E. coli. There is just not a system there to detect these kinds of microbial pathogens and organisms. So, as a result, the public is open to unsafe food. There is a responsibility from the public standpoint to make sure they prepare the food properly. There is ignorance out there.

Dr. Woteki talked about the need for education efforts. There needs to be an entire system here. You can't—it is hard to take pieces of it and say we need this and we need that. We need to stand back and look at the entire food safety system and start designing a system that gives the public confidence that it is safe.

Mr. TOWNS. Thank you very much.

Mr. Ebbitt, what did your office find at the Cornhusker plant when you revisited the plant at the request of the subcommittee? What did you find?

Mr. EBBITT. Mr. Chairman, we found that the plant had, in fact, corrected some of the major deficiencies that we found when we first visited there in June.

One of the things that they corrected was a driveway outside the plant leading up to the doors to the kill floor which should have been cement. Instead, it was stone/gravel, ideal for rodents. The plant did re-cement that. They made other corrections to keep rodents out. They did some other things as far as fixing the floors to improve rodent control.

Mr. TOWNS. But you would say that you did find continuing sanitation problems?

Mr. EBBITT. Yes, sir, we did.

Mr. TOWNS. Given the long history and gross violations at this plant that you cite in your August report, why doesn't FSIS just shut this plant down for good?

Mr. EBBITT. That is a good question, Mr. Chairman. What FSIS has done is increased the level of inspection to the stage 2 inspection level, which calls for more intensified inspections by FSIS. We believe that the plant management shares in the responsibility, and until such time as plant management turns their attitude around to really work with FSIS to correct problems in the long run, I don't think the situation is going to get much better.

Mr. TOWNS. Let me ask you this, then. Is the Cornhusker plant, is this an isolated case or are there other plants across the country with similar histories of compliance problems?

Mr. EBBITT. We were very concerned when we first visited Cornhusker to find out what was happening at the other plants under the control of the same circuit supervisor. We visited those plants and we didn't find the same kinds of problems.

What we recommended to FSIS was that they develop a profile using Cornhusker as an example to try and find out if there are other plants out there like Cornhusker. I think it needs to be clear that the conditions we saw at Cornhusker can't be extrapolated to other plants. What we saw at Cornhusker we only saw there.

Right now, FSIS is in the process of working with their regional offices to get that profile of Cornhusker out to the regional offices and get feedback from their regional offices as to whether or not there are other plants out there like Cornhusker. It is safe to say that FSIS does have a number of plants that are problem plants and that FSIS, when they have problem plants, puts those plants on the intensified inspection process.

Mr. TOWNS. Thank you very much. I see the red light is on, but let me quickly ask you, Mr. Harman, how much would it cost to develop a single food safety agency that you talked about? How much would it cost?

Mr. HARMAN. That is really hard to say. There would certainly be savings that would accrue from doing away with some of the duplication but it could very well be that you would increase inspections in some food products that are not currently inspected but every 3 to 5 years, and you may decrease inspection of some other products like meat if you went to some type of HACCP system, that is identifying the risk areas and inspecting the risk areas and going after problem plants like this on an intensified basis and bringing some penalties to bear on those plants.

Also, it would depend on how you funded it, to the extent user fees can be brought into the situation. It is really difficult to say, but we are talking about $1 billion, which is what the government is spending right now. Whether that would go down significantly or up to any extent depends upon the type of system you end up bringing into this single agency.

Mr. TOWNS. Maybe—the light is on, and let me just quickly—maybe I should have asked this question this way: Would you support the recommendations that have been made by the Vice President to move all responsibility for food safety into FDA or would you feel stronger toward creating a single, separate agency?

Mr. HARMAN. I think we would feel more comfortable with a single agency. FDA has its problems, too, and also has its problems with consumer confidence. I think it would be better if you stood back and created a separate agency. It could be within HHS, but it would be a health-related type of agency that you create.

We feel, based on the years of work we have done, we would feel a lot more comfortable with that. We think it may be politically easier to do, too.

Mr. TOWNS. Thank you very much. My time has definitely expired.

Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. You had a good line of questioning and I will be brief because I think you covered the relevant questions I had in mind.

Mr. Ebbitt, I understand you are with the Inspector General's Office of the U.S. Department of Agriculture. Is that right?

Mr. EBBITT. That is correct, sir.

Mr. SCHIFF. Because of that, because that is not specifically a policymaking body, I assume.

Mr. EBBITT. That is correct.

Mr. SCHIFF. You oversee the requirements set by the Secretary. I don't mean to make you personally the point of this, but let me tell you what I am hearing. I am hearing from you as you relate back to what your agency is doing that you are employing a great deal of—I have to say—of customary bureaucratic language.

We are working on this, we are trying to get the bugs out of the system and we are trying to adapt to the current problems, while I hear Dr. Blake from the Centers for Disease Control who testified on the panel right before you say that we are on the verge of an epidemic in this country.

I think that if we are going to try to prevent more parents from sitting in front of us like the parents we heard from a few minutes ago, I think that when the Department testifies here later through a policymaking representative, the Secretary or his designee, I sure hope they are just not going to say they are working on it.

I hope they lay before us exactly what they are doing, going to do, and if not, they are going to be tremendously failing in their responsibility as far as I am concerned.

I yield back to you, Mr. Chairman.

Mr. EBBITT. I would agree with that, Mr. Schiff. And I would also point out that like GAO, the Inspector General's Office since the mid-1980's has been talking about problems with meat inspection at USDA. We have talked about trace back. We have talked about microbiological testing, and all the things that have been talked about here this morning. I just wanted to point that out.

Mr. TOWNS. All right. Thank you.

Mr. SCHIFF. I appreciate that.

Yield back, Mr. Chairman.

Mr. TOWNS. Congressman Payne.

Mr. PAYNE. Thank you very much. Unfortunately, Mr. Chairman, I missed most of the testimony here, but I would certainly like to commend you for holding this very important hearing and I know that many Americans were certainly concerned when, back in No-

vember, we heard about this for the first time, to a large degree that E. coli outbreak that was caused by undercooked hamburgers.

I think that it is very, very important, as we all know, because of the fact that, unfortunately for the health of Americans—although maybe those who are in the business look at it differently—since there are so many fast foods being prepared for consumption in this country, there must be some guarantee that what is going to be picked up at the takeout counters and eaten at these various fast food places is safe to consume. We have to be sure, and we all as bureaucrats and legislators know, that if we ever get to the point where the credibility of the food industry is questioned, I think it is going to certainly have a very negative impact on that industry.

So it would appear to me that as the previous Speaker stated, that—at the moment I have no questions—but it is something that is on the minds of many people. We in this country have a lot of faith in the USDA, the FDA, those agencies, and we would hate to see the credibility of the agencies in question. Whether it is for medications or food inspection.

So I would hope, Mr. Chairman, that this hearing will start us on the road to having the remedial types of corrections that are necessary in order to maintain the integrity of those systems.

I am also disturbed that the Department of Agriculture did not send a person that could talk about what is going on now and what are the new trends.

I think we should attempt to have another hearing and to try to get the proper witnesses here that can update us as to where we are.

I yield back the balance of my time and would like to have an opening statement put into the record.

Mr. TOWNS. Without objection. So ordered.

[The prepared statement of Mr. Payne follows:]

Rep. Donald Payne (D-NJ)
Hearing--HRIR
Opening Statement
November 4, 1993

Good Morning. I want to begin by commending the Chairman for his leadership in calling this hearing on this very important topic. I would also like to extend my regards to the panel of witnesses who have agreed to provide us with their testimony.

Food safety is very important to our society and this issue is causing increasing concern.

On November 15, 1992, an outbreak of a potentially deadly and infectious strain of E. coli that lasted through February 28, of this year caused more than 500 illnesses and 4 deaths in 4 Western states. This outbreak was linked to undercooked hamburgers from the fast food chain, Jack-in-the-Box. USDA traced the hamburgers to slaughtering and processing plants that distributed contaminated meats.

Since then, at least nine subsequent outbreaks have surfaced since that initial outbreak almost a year ago and the incidence of E. coli infection is increasing.

I was disturbed to learn that CDC researchers estimate that between 7,670 and 20,450 people die annually in the U.S. due to that particular strain of E. coli, 157:H7. But, what is particularly disturbing to me is that the current system of meat and poultry inspection is not adequately designed to detect and control microbial pathogens in these foods.

I am sorry that there is no representation from the Department of Agriculture to respond to this issue and perhaps shine some light on a very alarming trend. At a future date, I hope that we will have an opportunity to discuss this with the people responsible for developing the guidelines for monitoring meat and poultry safety.

Mr. Chairman, I would like to thank you again for bringing this very important issue to our attention and I look forward to hearing what our witnesses have say.

Mr. TOWNS. Let me say to the gentleman, I agree with you that we must clean up our act, no question about it, and to also further add that the Department of Agriculture will be testifying on November 19.

Mr. PAYNE. Great, thank you.

Mr. TOWNS. Congressman Mica.

Mr. MICA. Thank you, Mr. Chairman.

I, too, came a bit late, but I had a chance to review some of the background information for this hearing and, quite frankly, I find some of the status of the USDA reform initiatives to be lacking and somewhat alarming. It seems these incidents were brought to the public's attention by these tragic deaths, and not much has been done.

I know we have got Mr. Harman who is with the GAO, and also the Assistant Inspector General, Mr. Ebbitt. But just some of the things that I understand that have not been done is that here on October 4, 1993, we asked Secretary Espy to provide a status report on USDA's initiatives. Specifically, we asked him to provide a description of the estimated level of effort needed to achieve the objective, staff years and resources and the projected timetable to completion and the results to date.

The Department has not yet complied with this request.

Then we go on and we look at a few of the examples that demonstrate the uncertain status of USDA's commitment to reform or for taking reform initiatives. May 27, they announced that within 90 days, they would be requiring plants to adopt HACCP procedures, and then we learned in September that that had been postponed.

We find that an interim rule was published in the Register relating to requiring safe handling instructions on meat and poultry. The judge blocked that rule, and to date, the Department doesn't appear to have done anything to counter that particular decision. The judge said that USDA developed the interim rule in an improper manner.

Then on May 27, Secretary Espy announced that within 30 days, at the end of public hearings, USDA would present a package of legislative proposals to strengthen USDA's authority. The hearings ended and they did conduct hearings. That seems to be the only thing we have gotten out of this as a tangible result. But the Department has not yet forwarded its legislative proposals to us.

It appears that the agency is not responding.

Now, one of you is in a GAO position, the other is in an IG position; what is your response?

Mr. HARMAN. I would say I would agree with that, Congressman.

This is not a new issue as I testified earlier. In 1977, I think the microbial pathogen issue first came out and recommendations made for FSIS—not FSIS at that time, but for USDA to develop some testing methods. That is some period of time to be able to do it and we are still here and the National Academy of Science has done significant work.

Mr. MICA. I don't mean to interrupt, and you agree, that is fine, but you are in an oversight position. What is going on at USDA? Why can't they respond? Is there a—I know for a fact that for many months there were not people in place.

Now, do we have incompetence in place or——

Mr. HARMAN. No, there are two parts involved in what they are trying to do. One is just to shore up the current system. We have certain doubts and I think it is backed up by a lot of support that that is not going to do the job.

The second part has to do with developing a completely new type of system based on HACCP, and they have just not been able to get off the dime on that. Some of it has to do with getting all the various groups that they have to bring into that situation to agree. Some of it has to do with just change, in and of itself, and how quickly you bring about that change.

I don't know if Mr. Zadjura can give any more details on that. He has been heavily involved in this. He is on my staff.

Mr. MICA. They have a plan. Do they have the resources to do this or is it a resource problem? They just can't decide on which direction to go?

Mr. HARMAN. We are talking about a major shift in regulatory approach.

Mr. MICA. OK.

Mr. HARMAN. That is what we are talking about. When you make a major shift, there will be winners and losers.

Mr. MICA. Nobody is willing to make that decision.

Mr. HARMAN. Since 1985 when NAS came out with their report, there were efforts from 1986 to 1992 to make major changes that didn't happen. That is not all because the unions disagreed, that is not because the consumer groups disagreed, it is because I think there was not good planning and good strategy and ways to bring those people into the process and to make it work.

Mr. MICA. When do you think the Department will bring some legislative proposals before the subcommittee chairman or the committee for consideration?

Mr. HARMAN. I don't have any indication right now of any date. Do you have any?

Mr. ZADJURA. No.

Mr. HARMAN. It's open ended.

Mr. MICA. Mr. Ebbitt, do you talk to the Secretary from time to time?

Mr. EBBITT. On occasion, Congressman.

Mr. MICA. Good. Would you tell him that I am still waiting patiently with baited breath for a reply to my letter to him dated, I think, September 23 when you see him? Every time I see somebody from USDA, I ask that question.

Mr. EBBITT. I will relay that message.

Mr. MICA. Do you think they have the resources and commitment to tackle this problem, or maybe it is just a problem that we—the government and USDA and FDA can't respond to?

Mr. EBBITT. Congressman, I think Secretary Espy has certainly voiced his commitment to try and deal with this problem. I would agree with what Mr. Harman said in that there are a lot of players including the scientific community and some folks that have testified here today. All have input into the process, and all I really know is that the Department, excuse the expression, but the Department, as I know, it is working to try and bring those issues to-

gether to decide which is the best approach and how to go about this.

Mr. MICA. Well, finally, just a final question, I notice in this one plant inspection case, Cornhusker?

Mr. EBBITT. Yes, sir.

Mr. MICA. Really the same incidents that were found in 1993 were found in 1987. Are there not any procedures to followup on these incidents? It seems like 5 years of repeated offenses.

Mr. EBBITT. There are, Congressman, and the plant should have been followed up. As I testified, there was a total breakdown in that process and in communication between in-plant inspectors, the circuit supervisor, and the area supervisor. Since then, of course, FSIS at that plant has taken drastic action to try and get the plant to where it needs to be.

Mr. MICA. Just my final comment, and you are all in oversight positions, anything you can do to move this along would be well received. We have a responsibility just like the Department does to the public health, welfare and food safety, but if we don't have the agency responding, if the agency can't respond in 5 years to an incident or incidents that we know take place, and has not met any of the timetables or proposed initiatives that are necessary to resolve this problem, we have got a big problem.

So I appreciate your cooperation in that regard. I yield back, Mr. Chairman. Thank you.

Mr. TOWNS. Thank you very much. Let me just say to the gentleman that the Agriculture Department has agreed to testify on November 19. I want to assure you of that. Let me thank the witnesses for your testimony. You have been extremely helpful. Thank you very, very much.

I would like to call on our third panel: Carol Tucker Foreman, representing the Safe Food Coalition; Dr. Bailus Walker, representing the American Public Health Association. Dr. Lester Crawford, representing the American Veterinary Medical Colleges; Dr. Edward Menning, representing the National Association of Federal Veterinarians; David Carney, representing the National Joint Counsel of Food Inspection Locals; and Gary Wilson, representing the National Cattlemen's Association.

It is the custom of the Government Operations Committee to ask all witnesses who present testimony before the committee to be sworn in. May I ask that you raise your right hand.

[Witnesses sworn.]

Mr. TOWNS. Please take your seats.

Let the record show that the witnesses answered in the affirmative.

Let me begin by thanking all of you for coming. Mr. Wilson, we are especially grateful for your participation and hope that other industry representatives will work with us as we review USDA's progress in reforming meat and poultry inspection.

Let me remind the witnesses to summarize your statements within 5 minutes. As you know, there is a light there and it starts out green, and when it turns red, that means your 5 minutes are up.

So I would hope you would respect that. That will allow the Members an opportunity to raise specific kinds of questions.

Why don't we begin with you, Ms. Foreman.

STATEMENT OF CAROL TUCKER FOREMAN, PRESIDENT, FOREMAN AND HEIDEPRIEM, INC., ON BEHALF OF THE SAFE FOOD COALITION

Ms. FOREMAN. Thank you. I am here today representing the Safe Food Coalition which is a group of consumer, public health, whistleblower and labor organizations. The coalition was formed in 1987 to work for improved meat and poultry inspection programs.

The American Public Health Association, represented here today by Dr. Walker, is one of our members.

My testimony includes a detailed plan for what our coalition thinks needs to be done to make meat and poultry inspection work better. I will forgo that for a shorter statement.

Mr. TOWNS. Let me indicate that your entire statement will be included in the record.

Ms. FOREMAN. Thank you, sir. You have heard from earlier witnesses of terrible suffering and death from foodborne illness and the statistics on the widespread nature of foodborne illness in the United States. E. coli 0157:H7 is just one of the bacteria in meat and poultry that cause serious illness.

Mr. Chairman, inertia, ineptitude and industry influence in the Department of Agriculture play a large role in the continuing problem that we have in this country with foodborne illness. I have brought several posters today, there are four of them here, that go through in detail USDA's failure to do the things that they said they would do to improve the problems. Mr. Mica is exactly right. It extends through Democratic and Republican administrations.

The FSIS has failed most recently to follow through on the recommendations of both the National Academy of Sciences and on the pledges that Secretary Espy made last January after the E. coli outbreak.

And 8 years after the National Academy of Sciences recommended rapid tests to detect bacterial contamination in meat and poultry and 9 months after the Food Safety and Inspection Service said such tests were a high priority, FSIS has no tests, no goals for when they will be developed, and no timetables for developing them. The agency has, after 8 years, published in the Federal Register a notice of the criteria staff thinks would be appropriate for such tests.

USDA recognized the need to be able to trace contaminated meat from the slaughterhouse back to its source 13 years ago. When I was Assistant Secretary of Agriculture, we sent to Congress a request that Congress give us that legislative authority. The legislation died at the end of the Carter administration, and was never reintroduced in the Reagan administration or the Bush administration.

Secretary Espy promised in February that this was a priority for his administration at USDA.

On September 13, the Department acknowledged that it did not have legislative authority to trace back contaminated product and that they were drafting a package of legislative proposals to do it. You don't have those proposals today. Congress is scheduled to leave on November 22.

Eight months after FSIS set a zero tolerance for fecal contamination it is not being enforced in some plants and there are no written guidelines in effect to enforce that regulation.

Eighteen years after the courts said the Secretary of Agriculture has the authority to require safe food handling labels on meat and poultry, 8½ years after the National Academy of Sciences made the same recommendation, 9 months after Secretary Espy told the Senate Agriculture Committee that the Department would require such instructions, there is no requirement for safe handling labels in effect.

After endless delay and numerous promises, nothing has changed. So when the Department comes here on November 19, I think you might start by saying, "Don't give us more promises. Tell us why nothing has happened."

By the first anniversary of the E. coli outbreak, not one of the pledges that I have mentioned here will have been fulfilled. Mr. Chairman, if the inertia and ineptitude and industry influence continue to dominate the program, we may all be back here next year after more children have died.

That is just not acceptable.

Mr. TOWNS. Thank you very much for your testimony.

[The prepared statement of Ms. Foreman follows:]

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Statement of
CAROL TUCKER FOREMAN[1]
Before the
Subcommittee on Human Resources
and Intergovernmental Relations
COMMITTEE ON GOVERNMENT OPERATIONS
UNITED STATES HOUSE OF REPRESENTATIVES
November 4, 1993

Mr. Chairman, I am Carol Tucker Foreman. I appear today on behalf of the following members of the Safe Food Coalition:[2] Consumer Federation of America, Consumers Union, Food and Allied Service Trades Department (AFL-CIO), Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, and United Food and Commercial Workers International Union.

The Committee has asked the coalition's views on four issues: the extent to which the existing federal meat and poultry inspection system is designed to reduce risks of foodborne illness; suggestions for redesigning meat and poultry inspection to be health-based; USDA's progress on reforming meat and poultry inspection; and consolidating food safety responsibilities in one agency.

I. THE CURRENT MEAT AND POULTRY INSPECTION SYSTEM IS NOT ADEQUATE TO MEET THE CHALLENGE OF FOODBORNE ILLNESS

Americans expect their food to be safe. Both U.S. government and industry officials frequently claim that U.S. consumers enjoy the safest food supply in the world. The Department of Agriculture reenforces this claim by stamping every package of meat and

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[2]The Safe Food Coalition, an alliance of consumer advocacy, senior citizen, whistleblower protection and labor organizations was formed in 1987 to work for improvements in the nation's food inspection programs. Consumers Union is not a formal member of the Coalition, but endorses this testimony.

poultry with a seal stating it has been "inspected for wholesomeness and passed by the U.S. Department of Agriculture."

Despite the assurances, our food isn't safe enough. The E. coli 0157:H7 outbreak was just the most recent and dramatic evidence of a serious public health problem. According to the Centers for Disease Control and Prevention (CDC), there are between 6.5 and 80 million cases of and 9,000 deaths from bacterial food borne illness each year in the U.S. USDA's Economic Research Service has estimated that foodborne illness costs this nation about $2 to $4 billion each year in medical costs and lost productivity. All of these figures are conservative estimates because the foodborne disease reporting system is acknowledged to underestimate the number of illnesses and deaths.

The CDC reports that some types of foodborne illness are increasing and suggests the increase may be traced to a number of factors. Today's food supply is highly processed, shipped across country, and increasingly, imported from other countries. Eating habits have changed. Americans eat on the run, stopping at a fast food restaurant, purchasing partially prepared or frozen food to be finished in a home microwave. As a result, bacteria have a greater opportunity to increase to a critical level.

Foodborne illness is likely to continue to increase because the most susceptible people, those whose immune systems are weakened by age or disease, are increasing. Further, new strains of bacteria continue to evolve, creating new challenges.

The most common sources of bacterial foodborne illness are meat, poultry, eggs and shellfish, and it is clear that major changes need to be made, from production to consumption, in the way food is grown and processed, and how it is handled by retailers, food service personnel and consumers.

After hearing the heart wrenching testimony of parents who have lost children to E. coli 0157:H7 and other deadly foodborne illnesses, it is clear that the system must be improved.

Because meat and poultry are a major source of bacterial foodborne illness and because meat and poultry slaughter and processing are the only parts of the food production system where the United States government inspects all products and asserts that they are wholesome, we should attack the problem of bacterial foodborne illness by addressing the flaws in the slaughtering and processing part of the system first.

The federal meat and poultry inspection system costs the American taxpayer $600 million yearly. We are not getting good value for that money. Problems with the system include:

1. The system is heavily reliant on old fashioned "organoleptic" methods. These methods rely on sight, smell, taste and touch to determine if food is safe. Unfortunately, pathogenic bacteria cannot be seen, smelled, tasted or felt.

2. The pressures of increasing meat production on inspection resources, twelve years of deregulation and the growing need to control government spending have compelled USDA to approach inspection reform by emphasizing ways to cut spending instead of developing ways to protect public health more effectively.

3. USDA historically has been dominated by producer and animal health interests rather than consumer and public health interests.

4. The Department of Agriculture and the Food Safety and Inspection Service have been unable to set reasonable goals for improvement and meet them in a timely fashion.

II. USDA HAS NOT MADE ACCEPTABLE PROGRESS TOWARD RESOLVING THE PROBLEMS THAT PLAGUE THE MEAT AND POULTRY INSPECTION SYSTEM

Secretary Espy had barely assumed his new office when he was confronted by the terrible West Coast E. coli outbreak. The Secretary was obviously distressed by this tragedy. He and FSIS Administrator Russell Cross pledged strong action including:

o developing rapid on-line tests to detect bacterial contamination in raw meat and poultry,

o enforcing a "zero tolerance" for fecal contamination of meat and poultry,

o requiring safe food handling labels for meat and poultry products, and

o establishing a system to trace bad meat or poultry from the slaughterhouse back to its source.

Those are all good ideas. None of them is new. Some have been around for 20 years. Yet, as of today, not one of the goals has been met. It is unlikely that any of them will have been implemented by the first anniversary of the E. coli outbreak.

No one doubts Secretary Espy's sincerity. I am sure he is unaware of just how often FSIS officials have made those same pledges and failed to meet them, or, in fact, made any

real progress toward meeting them. The Safe Food Coalition challenges the Congress and the Administration to take the steps necessary to change this pattern of failure.

Let me describe the history of the problem, the promised change and the progress to date on several important issues.

THE FAILURE TO DEVELOP RAPID ON-LINE TESTS FOR BACTERIAL CONTAMINATION OF RAW MEAT AND POULTRY.

Eight years after the National Academy of Sciences recommended that USDA develop rapid on-line tests to detect bacterial contamination of raw meat and poultry before the product leaves the plant, the Department has made no progress toward this goal.

The 1985 National Academy of Sciences Report, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program stated:

> "FSIS (should) intensify its current efforts to control and eliminate contamination with microorganisms that cause disease in humans. Such efforts should include evaluation of rapid diagnostic procedures for detecting microorganisms, especially species of salmonella and campylobacter." (National Academy of Sciences, Meat and Poultry Inspection: the Scientific Basis of the Nation's Program (hereafter referred to as NAS), 1985, p. 4)
>
> "As of 1984, only a few quick tests have been developed, although it is widely recognized that online serological testing of animals could dramatically reduce the need for subjective decision making that has marked meat and poultry inspection for nearly a century. The committee maintains that much more could have been done by now." (NAS, p. 161)

Almost exactly four years later, on April 11, 1989, FSIS Administrator Lester Crawford testified before this Subcommittee and acknowledged that the Agency had not yet begun developing rapid tests for bacterial contamination. He stated,

> "analytical testing...including both laboratory and rapid in-plant tests to detect contamination..." were part of "the next phase" of the Agency's program. (U.S. House of Representatives Committee on Government Operations, April 11, 1989, p. 180)
>
> Dr. Crawford stated further,
>
> "We are developing a proposal announcing criteria for streamlined approval of new diagnostic and screening tests"...for microbial and chemical contamination. (Committee on Government Operations, p. 171)

In February 1993, the present FSIS Administrator Russell Cross replayed the theme,

> "Regrettably, there is no in-plant test developed and approved for microbiological testing of raw meat and poultry products. This is one of our highest research priorities and we expect significant progress in this area in the future." (Testimony before Washington State Senate, February 2, 1993)

On October 21, 1993, FSIS published in the Federal Register a notice to inform interested parties of the criteria that FSIS will use to evaluate and/or develop new test results. The notice included such criteria as the need for "faster results" than the present 24-hour tests.

Mr. Chairman, eight years and six months after the National Academy recommendation, four years and eight months after FSIS said the tests were a priority and pledged to publish criteria for them, and nine months after the new Administration said rapid tests were a high research priority, the Agency has not developed the tests, nor let any contracts to develop the tests, nor set any goals or timetables for developing the tests. After all this time, FSIS has only decided what the criteria are for an adequate test.

The truth is that USDA has avoided developing the tests because the Agency has maintained for years that it does not have authority to set or enforce bacterial standards. If the Agency had rapid tests, it would have to have some sort of guideline for how much bacterial contamination is too much.

On June 10, 1991, Dr. Crawford told a meeting of the National Broiler Council,

> "USDA does not now have the authority to impose microbiological criteria on raw meat and poultry products. However, Congress, fed by misinformed public perceptions and pressured by misleading, so-called consumer activists, may direct us to do so." (Dr. Crawford's remarks before the National Broiler Council, Hilton Head Island, S.C., June 10, 1991, p. 5)

On January 22, 1993, Administrator Cross reiterated the position taken by Dr. Crawford. In a memorandum to Secretary Espy, he said,

> "Congress did not intend the prescribed official inspection legends on meat and poultry produce to import a finding that the products were free from salmonellae and other bacteria in that Congress did not intend that inspections include 'microscopic examinations.'" (Cross memorandum to Sec. Espy, January 22, 1993, p. 1)

I would like to submit for the record copies of legal memoranda, including one from a former USDA general counsel that effectively rebut that notion.

USDA now takes a slightly different position on rapid testing. Both Secretary Espy and Administrator Cross have argued in congressional testimony that "adequate" bacterial testing of meat and poultry would cost nearly $58 billion. (Senate Committee on Agriculture, Forestry and Nutrition, p. 12)

Ed Zadjura, assistant director of food safety at the General Accounting Office, replied, "that number is totally, absolutely meaningless. Nobody who has advocated bringing this system into the 20th century has advocated checking every piece of meat." USDA budget officers say they were told to estimate a $50 cost per test for checking 20 percent of the meat. Zadjura questioned the cost of the test and stated that testing 1 percent should be sufficient. ("Where's the Beef Been," Washington Monthly, June 1993, p. 21)

THE FAILURE TO DEVELOP GUIDELINES AND ENFORCE A "ZERO TOLERANCE" FOR FECAL CONTAMINATION OF BEEF CARCASSES.

Feces, milk and ingesta may harbor dangerous bacteria that cause E. coli, salmonellosis and campylobacteriosis.

Secretary Espy announced eight months ago that USDA would strictly enforce a policy of "zero tolerance" for beef contaminated with feces and told the FSIS to come up with a set of rules to implement the policy. (Seattle Post-Intelligencer, Oct. 29, 1993)

On March 3, 1993, Dr. Wilson Horne of FSIS sent a memorandum to "Inspectors-in-Charge and Plant Operators Beef Slaughter and Boning Plants" stating,

> "Effective immediately: 1. All fecal, ingesta and milk contamination, from any source, must be trimmed prior to any washing of the carcass 2. Any and all acceptable quality level (AQL) standards for feces and ingesta on carcasses or boneless beef are suspended and a zero tolerance for feces and ingesta is to be enforced." (Horne memorandum to inspectors, March 2, 1993)

However, industry officials complained and one wrote that he had been assured the new policy would not cause his company any real inconvenience. He wrote,

> "The zero tolerance is for 'obvious' fecal and ingesta contamination...if the inspectors are calling non-obvious specks, they need to be challenged as to how they know it is fecal and/or ingesta." (D. Allen memorandum, see attached)

> "Please keep us informed and it would not hurt to provide me with names of inspectors who seem to get out of line on this." (D. Allen memorandum)

> "Russell asked me to contact Dr. Nelson in Dallas which I did. He also said that anything that happened that appeared to be a knee-jerk reaction by an in-plant

and/or circuit supervisor should be reported immediately to the regional office." (D. Allen memorandum)

"The message from Dr. Nelson and Russell was the same. Both said to immediately call the regional director if there seems to be an un-fair and/or un-usually [sic] severe intrepretation [sic] of this action." (D. Allen memorandum)

As of last week there were no published guidelines for enforcing the zero tolerance policy. In an article published October 29, 1993, the Seattle Post-Intelligencer reported that the latest of several versions of the regulations: assigns responsibility for selecting carcasses to be tested to plant employees rather than inspectors; allows inspectors to monitor the sampling of less than one percent of the carcasses; retreats from the original requirement that sampling occur before carcasses are washed and now allows it to occur after washing. (Washing scatters the feces into specks that can't be seen, but still harbor bacteria and the spray wash imbeds feces in the carcass.) USDA's program may simply institutionalize germs originating from fecal contamination.

THE FAILURE TO DEVELOP A ZERO TOLERANCE POLICY FOR POULTRY.

Poultry carcasses are frequently soiled by feces and ingesta and some USDA studies indicate that up to 60 percent of broiler carcasses are contaminated with pathogenic bacteria.

In May, Secretary Espy told a press conference that he wanted to extend the "zero tolerance" policy to poultry. He stated that the Department was working with the poultry industry, "but also consulting consumer groups to see if we can come up with something that everyone can live with." (Meat Inspection Press Conference Transcript, May 27, 1993, p. 10-11) As of today, the FSIS has never contacted any of the public health or consumer organizations that belong to the Safe Food Coalition to discuss this problem.

The guidelines circulated last week do not include rules for enforcing zero tolerance in poultry nor do they set a date by which the Department expects to have such rules. It is currently USDA's policy to allow poultry contaminated with feces to wear the "inspected for wholesomeness" label.

THE FAILURE TO PLACE "SAFE HANDLING INSTRUCTION LABELS" ON MEAT AND POULTRY PRODUCTS.

Perhaps the most painful example of USDA's inability to actually effect a change to protect public health is the twenty year effort to get safe handling instructions put on meat and poultry.

On February 5, 1993, Secretary Espy stated,

"The third thing we can do is improve and promote safe handling labels, and improve the instructions for cooking and the handling of raw meat and poultry... So we need to move right away to developing instructions to promote safe handling and cooking of raw meat and poultry, particularly hamburger." (U.S. Senate Committee on Agriculture, Forestry and Nutrition, February, 5, 1993, p. 12)

Despite this pledge, the Agency did not issue requirements for safe handling labels immediately. In June 1993, after USDA was sued by the Beyond Beef Campaign, the Department agreed to publish regulations for such labels by August 15, 1993.

USDA met that commitment. The Department published an interim final rule requiring that labels be applied by October 15. Consumer and public health groups reacted favorably. However, the Department was not able to persuade the federal courts that it was justified in bypassing the usual notice and comment rulemaking and there is, as of today, no requirement for safe handling labels in effect.

The U.S. Court of Appeals refused an expedited hearing of USDA's appeal of the district court decision and the case was scheduled for a hearing in January 1994. Last Friday, USDA announced it would drop its appeal of the decision throwing out the labelling regulations. The Department now plans to issue proposed regulations, allow comments and then publish a final rule.

As a result of this befuddled regulatory process, there will be no federally mandated safe handling label regulations in effect on the first anniversary of the West Coast E. coli outbreak passes in January.

USDA's recent inability to get regulations written in a timely and legal manner, has been widely reported, Mr. Chairman. What is less well known is that another federal court decision, handed down 19 years ago, declared that USDA has the authority to require safe handling labels. The U.S. Court of Appeals ruled that the provisions of the meat and poultry inspection acts "give the Secretary discretion to determine what labeling, if any, will be required in addition to the official inspection stamp." APHA v. Butz, 511 F.2d 335 (D.C. Cir. 1974)

The case was filed by consumer activists seeking important health information. For 20 years, the Department has simply refused to use its authority to provide labels.

Further, in 1991, after widely publicized outbreaks of salmonella and campylobacter food poisoning, the National Advisory Committee on Microbiological Criteria for Food (NACMCF) recommended safe handling labels be placed on meat and poultry.

On June 10, 1991, Administrator Lester Crawford urged poultry producers to put instructions on their products. Later that summer, FSIS announced it would issue regulations for acceptable wording in voluntary safe handling labels. The Agency never completed action on that regulation.

The Secretary's pledge to get these labels on meat and poultry should not have been a surprise to FSIS. The Agency had had twenty years to draft a regulation. But, after all that time, after twenty years, FSIS was unable to draft regulations, allow comment and issue rules for safe handling labels in a timely fashion. As a result, the public still remains without a legal requirement for safe handling labels. Frankly, given the record, I wouldn't make any bets that the rules will be in effect for all meat and poultry a year from now.

Many meat processors and retailers have voluntarily placed labels on meat and poultry. My suburban supermarket has labels on its products. However, my guess is that people who are dependent on small shops, especially those in the inner city that serve low income people, will remain without protection for some time to come.

THE FAILURE TO INSTITUTE A SYSTEM TO TRACE CONTAMINATED MEAT AND POULTRY FROM THE SLAUGHTERHOUSE BACK TO ITS FARM OR FEEDLOT SOURCE.

The best place to stop contamination is at the source. However, USDA has no program to trace beef or pork found to be contaminated with harmful bacteria or chemical residues from the slaughterhouse back to its point of origin.

On February 5, 1993, Secretary Espy said:

> "We can do more right away to improve the requirement that these federally inspected slaughterhouses keep better records. I would like to see that (traceback) become a standard throughout the slaughter industry." (U.S. Senate Committee on Agriculture, Forestry and Nutrition, February 5, 1993, p. 12)

Nothing more happened. No rule was proposed. On September 17, seven months later, Administrator Russell Cross told the Physicians Committee for Responsible Medicine,

> "It is not correct that we have dropped plans for a traceback system... USDA does not now have authority under the meat and poultry inspection acts to require mandatory animal traceback. Neither does it have authority to prevent the movement of animals to slaughter, except for certain infectious animal diseases...However, FSIS has prepared a series of legislative proposals...to give the Secretary authority to control human pathogens in food producing animals..."(Letter to Dr. Neal Barnard, September 17, 1993)

As of October 31, 1993, no proposed legislation has been submitted to the Congress. Since you are scheduled to adjourn on November 22 and not return until mid-January, there

will be no traceback system in place on the first anniversary of the E. coli outbreak. Once again, the Secretary's pledge languishes in the bowels of FSIS.

There was nothing in Secretary Espy's comments in February or in his May press conference that indicated USDA did not have legal authority to implement a traceback system. The career officials in FSIS knew the authority was lacking. Why didn't they tell the Secretary?

Traceback is not a new idea. It was endorsed by the NAS in 1985. Even that recommendation wasn't new. Consumer groups and some processors have advocated it for years. In 1980, the Department of Agriculture drafted, OMB cleared and the Carter Administration submitted to Congress a request for authority to trace meat and poultry back to their source.

Why didn't the Department indicate it would have to get Congress to approve traceback authority? Why has the Department still not submitted a bill to Congress? Why didn't USDA retrieve the 1980 bill and resubmit it?

Why has the Department of Agriculture failed to act on these and a host of other matters that would improve meat and poultry inspection? Why does a proposal to protect public health languish for twenty years? How can industry pressure unravel policies that the Secretary has ordered? Does anyone in the Agency feel an obligation to help the Secretary meet his public commitments? Is there anyone minding the store at the Department?

It is also fair to ask, where has the Congress been? Why haven't the Agriculture Committees asked these questions? With all due respect, sir, after effectively raising important questions in 1989, this Committee did not pursue them. We urge you to ask the Department to respond to the questions we have raised, and we urge you to come back in six months and judge whether the USDA has met the commitments it makes to you. If they have, it will be an historic first.

The public, especially the victims of the E coli outbreak and all of the other millions who have suffered from food poisoning over the past 10 to 15 years, has a right to know the answers to these questions. And they have a right to demand action.

Bacterial foodborne illness is not going to go away. Unless you act and demand that USDA act, we may all be back here again next year, listening to the tragic stories of another set of victims. That is just not acceptable.

III. DESIGNING A MEAT AND POULTRY INSPECTION SYSTEM THAT IMPROVES PUBLIC HEALTH PROTECTION

There is virtually universal agreement that the meat and poultry inspection system needs radical change. In 1985, the National Academy of Sciences laid out the basis for a science-based system designed to protect public health. However, USDA did not follow the NAS recommendations and much of the science necessary for a system that can reduce foodborne illness still does not exist.

We need a concentrated effort to develop the necessary data as quickly as possible.

DEVELOPING THE DATA FOR A NEW SYSTEM

The Clinton Administration should:

1. Contract with the NAS to develop infectious dose data for pathogens in meat and poultry. The NAS recommended this in its 1985 report as the first vital step in building an inspection system geared to public health protection. USDA must not attempt to build new systems without securing this data. It runs the risk that the new systems will not keep bacteria below a critical level.

2. Develop rapid tests for these bacteria that can be applied before raw meat and poultry products leave the plant; the 1985 NAS Report recommended development and use of these tests. The NACMCF suggests that microbial testing in Hazard Analysis and Critical Control Point System (HACCP) is of limited value in monitoring critical control points because it takes too long. (NACMCF, "Hazard Analysis and Critical Control Point System," March 20, 1992, p. 2) Rapid tests would help resolve this problem.

3. Direct the Food and Drug Administration to set guidelines for bacterial contamination in meat and poultry. FDA has established guidelines for bacterial contamination of raw seafood products and has the scientific capacity to set them for meat and poultry. FDA already sets the standards for acceptable levels of animal drug residues in meat. FSIS inspectors merely verify that meat and poultry meet the FDA guidelines.

4. Submit the results of the study on baseline data for microbiological contamination of beef to the NAS for verification of the efficacy of the study and develop similar data for poultry and pork. Scientists from other government agencies have been critical of the structure of the beef study. They state that samples are being taken at a place where contamination is least likely to occur and that the analytical methods being used are too insensitive to detect harmful levels of microbial contamination.

5. Determine the impact of processing and distribution on growth of bacteria in meat and poultry by gathering information on the microbiological profile of raw meat and poultry at the end of the production line and at the supermarket case by developing a vertical

sampling system to determine levels of bacterial contamination at every step from slaughter to final purchase.

This may help show how contamination occurs, what processing and distribution factors encourage bacteria to multiply and what steps might be taken to reduce bacterial contamination as much as possible, as quickly as possible.

6. Develop and require all processors to use marking devices that will indicate when a package of raw meat or poultry has been subjected to temperature abuse.

7. Contract with the NAS to develop the details of a HACCP system for meat and poultry inspection. The work done to date by FSIS is of very severely limited value because it is not based on a risk assessment, the essential first step in developing a workable HACCP program.

8. Put the government's and the nation's best, most creative scientists to work on the issues. The issue is sufficiently important to go beyond FSIS and the Agricultural Research Service. It is time to call on biological warfare and electronic detection experts, among others, who may be able to adapt their knowledge to meet the need.

The Safe Food Coalition recommends setting up two Interagency Task Forces to do this work:

o the first should be chaired by the Assistant Secretary for Health at the Department of Health and Human Services and should address how to develop the basic public health data needed to underpin meat and poultry inspection;

o the second task force, chaired by the President's Science Adviser and including representatives from the Department of Defense, NASA, and OTA, as well as FDA and CDC should be charged with establishing a competitive grant program and reviewing proposals for developing rapid online tests for microbial contamination of meat and poultry.

DEVELOPING A HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

The Safe Food Coalition, along with the NAS, the industry and the federal government, believes that HACCP holds promise for improving food safety and public health protection.

However, we believe it is important to understand the nature of HACCP, the extent of its application to food safety, how USDA intends to apply it to meat and poultry, and whether USDA's HACCP system will include elements which we believe are essential to its effective use as part of a government inspection system before we can endorse it as a step toward improved public health.

HACCP is not a health and safety regulatory program. It is a process control system that can be applied to virtually any type of manufacturing. It identifies points at which problems may arise and prevents the problem by controlling what happens at the points. Some food companies now employ HACCP systems primarily to improve the shelf life of their products. The only mandatory regulatory application of HACCP to food manufacturing is FDA's HACCP system for low-acid canned foods. That program has been very effective, but canned foods are cooked and, therefore, present different problems than raw meat and poultry.

SFC believes the following elements are essential to a HACCP system capable of improving food safety. We strongly recommend that they be incorporated in USDA's system:

1. **Develop a common definition and standard for all government food inspection HACCP programs.** There is little substantive information about HACCP as applied to meat and poultry, or the requirements for an effective program when HACCP is mandated as part of a government regulatory system.

2. **Demonstrate that the application of the USDA HACCP system will result in cleaner, safer food that is less likely to cause foodborne illness.** Theoretically, HACCP has the potential to improve food safety. Intuitively, we believe that it should be an improvement over the old system. Food safety, however, should not rely on intuition. USDA has no experience in creating or implementing a HACCP system. FSIS has no empirical evidence to demonstrate that HACCP, applied to the meat and poultry inspection system, will result in cleaner, safer meat and poultry that are less likely to cause foodborne illness.

The FSIS official in charge of HACCP has stated that the Agency does not expect to have such data before launching HACCP. Further, FSIS does not have any plans to pilot test HACCP in advance of its proposed or final regulations to demonstrate that its HACCP system will make food safer.

We believe FSIS should contract with the National Academy of Sciences Food and Nutrition Board to conduct pilot tests on the effectiveness of the proposed system. To determine if HACCP works across the board, these tests should be carried out in plants with records of excellent, mediocre and poor compliance and in operations of high, medium and low public health risk prior to implementation of HACCP. The testing and evaluation should be accomplished within a 6-9 month period.

3. **Set standards and guidelines stringent enough to reduce the likelihood of foodborne illness.** FSIS currently has no guidelines for bacterial contamination of raw meat and poultry. The Agency staff says HACCP will not have such guidelines. *It should.*

4. Develop data to demonstrate that the visual and physical tests applied in monitoring and verification are accurate and adequate to improve food safety. FSIS has indicated the HACCP system will use a number of the same visual and physical checks that are part of organoleptic inspection to monitor and verify critical control points. The agency should be able to demonstrate how these checks, applied in the HACCP system, will result in a safer product.

5. Submit the HACCP system to review by a qualified, neutral third party, such as the National Academy of Sciences. The review should include consultation with consumer, public health and other public interest groups.

6. Make available to the public all plant HACCP plans and records relating to actions taken by federal inspectors to enforce safety in HACCP plants. USDA's HACCP might constitute a massive "privatization" of a previously public function. Under the present inspection system, federal inspectors review plant operations each day and then sign an inspection report. The report notes any problems which had to be remedied to produce safe product and is available to the public. The NACMCF recommended that HACCP plans "must be considered proprietary information that must not be made available outside the regulatory agency." (Generic HACCP for Raw Beef, p. 36) FSIS should not follow this recommendation. The plans must be publicly available.

7. Undertake a full public examination of all issues related to HACCP before publishing regulations. The SFC is pleased to note that USDA seems to have recognized the value of this step. In late summer Assistant Secretary Branstool met with us and said he would organize a process in which all concerned parties could agree on and then discuss the key issues in a HACCP system. We had hoped and expected that meeting would occur in early December. We are eager to move ahead. We expect FSIS will publish a document laying out the key issues in HACCP and the options for addressing each of them. We expect the meeting to provide an opportunity for us to ask FSIS officials questions about each option, learn what benefits and drawbacks FSIS sees in each and express opinions on which is the best approach.

PROVIDING AN ADEQUATE LEGAL AND REGULATORY FRAMEWORK FOR A NEW INSPECTION SYSTEM

It is essential to establish in advance of its first application: the role FSIS expects HACCP to play in the future of inspection, the role FSIS will play in the design, implementation, management and evaluation of HACCP, and the regulatory framework for HACCP under FSIS.

FSIS officials state that HACCP will not take the place of existing inspection. However, on May 27, Administrator Cross stated that implementation of HACCP would have a "drastic effect on the way inspectors do their jobs." (Transcript of Press Conference, May 27, 1993) Other USDA and congressional leaders describe HACCP, not as an

incidental add-on to an existing system, but as the basic element of a new system. Finally, the NACMCF certainly anticipated that HACCP would replace specific tasks now carried out by inspectors.

Even though the inspection system may not change immediately, ultimately, it seems certain that the implementation of HACCP will lead USDA to propose ending the traditional "continuous inspection" that has characterized meat and poultry inspection.

SFC believes continuous inspection must remain in place until the following regulatory procedures are implemented:

1. **Unannounced, random inspections by federally sworn personnel, with frequency based on the risk associated with the operation being performed, the product being produced and the compliance history of the plant.**

2. **Independent certification of hazard analysis experts and of plant personnel conducting HACCP procedures.**

3. **Public access to all plant records related to critical control points, verifications, deviations and corrections.**

4. **Monthly publication of names of plants that violate HACCP requirements.**

STRENGTHENING STATUTORY AUTHORITY

If the nation wants to conquer foodborne illness, Congress must give the regulatory agencies the statutory authority to make sure the new system works. This will require changes to provide the food safety agency with:

1. Full Control from Farm to Consumer. The inspection agency needs statutory authority to: regulate the safety of meat and poultry products from the time that animals are raised on farms to the time that these products are sold to consumers, including traceback authority; issue regulations that would require good animal husbandry practices on farms; inspect farms to assure that these regulations are followed; and issue regulations to assure the safety of meat and poultry products while in shipment or storage.

2. Mandatory Recall Authority. The inspection agency needs statutory authority to mandate the recall of adulterated products. Currently, the agency must convince processors to voluntarily recall their products if they are considered hazardous to human health. If a processor is reluctant to do so, valuable time is wasted in trying to persuade the processor -- time that could be the difference between someone staying healthy and becoming ill. FDA has this authority to recall defective medical devices; and we believe similar authority is needed to recall unsafe food.

3. Authority to Impose Civil Penalties. The inspection agency must have authority to impose civil penalties on companies that violate inspection regulations or laws.

4. Whistleblower Protection for Plant Employees. If plant employees replace federal inspectors in providing public health protection, the law must protect them against losing their jobs if they report public health hazards.

IMPROVING THE EXISTING SYSTEM

There are steps that can be taken right this minute that can reasonably be expected to reduce bacterial contamination. The Clinton Administration should:

1. Bring new leadership to FSIS. These public health programs need the leadership of someone who brings an exceptionally strong record in development and administration of a public health program and a reputation for commitment to strong science. The Agency also needs to recruit a staff of public health experts to balance the existing staff that is heavily weighted to veterinarians and food technologists.

Recently, Secretary Espy stated that he would appoint a "public health advisor" to work with FSIS. The Administrator of the agency is a meat scientist, an expert in breeding cattle, not a trained public heath expert, not a scientist who knows how to develop programs to prevent foodborne illness in humans. Frankly the Secretary's suggestion adds insult to the injury of those who have suffered from foodborne illness. One or two "public health advisors" plopped down in the middle of an agriculture agency will not change the culture or create the critical mass needed for change.

Meat and poultry inspection is a public health program. The program should be led by a public health expert and staffed by human health experts, with an animal health advisor, not the reverse.

2. Restore the inspector's ability to protect the public. This should include the following actions:

- o Directing that no inspector may be harassed or face disciplinary action for carrying out written instructions or, where no written instructions exist, for acting on reasonable interpretations of previously announced policies.

- o Requiring company appeals of inspector decisions to be made in writing. An FSIS decision to overrule inspectors should be in writing, citing legal or policy grounds for the decision.

- o Publishing all overrule decisions and distributing to the public monthly.

o Reinstating the authority of inspectors to maintain high sanitation standards in plants.

o Restoring the inspector's authority to slow down or shut down plants for corrective actions to reduce contamination.

3. Reduce line speeds in plants where carcasses are contaminated with ingesta and fecal material until the problem is resolved.

One thing the Administration should not do is substitute the irradiation of dirty meat for improving the system. Despite the fact that the FDA has approved irradiation of poultry to kill pathogenic bacteria, there are a number of yet unresolved problems with this technology, and the public has not rushed to purchase irradiated poultry.

IV. ALL FEDERAL FOOD INSPECTION FUNCTIONS SHOULD BE CONSOLIDATED IN ONE AGENCY

In September, Vice President Gore's National Performance Review (NPR) recommended abolishing the Food Safety and Inspection Service (FSIS) and moving meat and poultry inspection to the Food and Drug Administration (FDA).

It isn't the first time this has been suggested. A number of Administrations have made similar recommendations. Two years ago, the General Accounting Office recommended that Congress consider combining food safety functions. We believe the time has come to give such a proposal serious consideration.

Mr. Chairman, it is very important that we all understand what the Vice President's report did not recommend. It did not suggest doing away with continuous inspection of meat and poultry in favor of the less intensive system employed by the Food and Drug Administration. There should be no question about the position of the Safe Food Coalition. Our group was formed in opposition to the Processed Products Inspection Improvement Act of 1986 that did away with continuous inspection in meat and poultry processing.

We have historically, and continue to insist that, until there is a scientific and technological breakthrough, until a less than continuous inspection system has been researched, developed, tested, evaluated and found to produce food that is cleaner, safer and less likely to cause foodborne illness, our Coalition supports continuous inspection.

We support moving meat and poultry inspection to a public health agency. We support moving the continuous system with it and we will fight to see that that happens. The present system isn't failing because it is continuous. That is its strong point. It is failing because USDA has an inherent conflict of interest in trying to administer this public health program. It is impossible to both promote the sale of agricultural products and protect public health. The NPR quite rightly recommended steps that will consolidate administrative

and scientific resources and, most importantly, put meat and poultry inspection where it belongs, in a public health agency.

There is no justification for meat and poultry inspection to be separated from the rest of food inspection. Our entire food safety system is a Rube Goldberg patchwork of laws that were passed over a span of almost 100 years in response to a variety of specific crises and special interests. There is no coherent, cohesive framework.

The presence of meat and poultry inspection in USDA is an historical anomaly that should end. At the turn of the century when the first Pure Food Act was passed, food was produced and consumed within a short time and a small radius. Most of the nation's population was rural. Many produced their own food. The Department of Agriculture represented a large portion of the nation's people, and the administration of all food safety programs was assigned to USDA.

Within a fairly short period, it became clear that producer interests had too much influence on food safety within the USDA. All food inspection, except for meat inspection was moved out of the Department to an institution more concerned with public health.

The responsibility for meat inspection was left in USDA because most of the human health problems that arose from the consumption of meat were the result of diseases passed from animals to humans. That is no longer true. It hasn't been true for a very long time, but special interests, comfortable with their relations within the Department, have fought furiously to maintain the status quo. Just since NPR recommended moving meat and poultry inspection, representatives of the meat and poultry industries and their good friends here in Congress have attacked the recommendations.

However, I suspect that if you venture out to your districts and ask any voter on the street if it makes sense to have milk from a dairy cow inspected by the Food and Drug Administration in the Department of Health and Human Services but ground beef from a slaughtered dairy cow inspected the Food Safety and Inspection Service in the Department of Agriculture, you will get a quick taste of how dumb most Americans think our government is. And they will be right. It is a truly dumb arrangement.

As we have seen, USDA lacks both expertise in human health and a commitment to public health. FDA is not without problems either. The Agency is located three levels down in the Department, is constantly denied adequate resources to do the jobs assigned to it, and does not have sufficient statutory authority to carry out its mandate.

The Safe Food Coalition believes the Administration should consider combining all food safety programs within HHS and elevating FDA to a level equal to the Social Security Administration or combining all food inspection in an independent food safety agency.

One approach might be to combine the food inspection functions of FDA and USDA and the pesticide programs of EPA with the responsibilities of the Consumer Product

Safety Commission and rename and reconfigure that agency so that it would be a Food and Consumer Protect Safety Agency. This is similar to the original concept for the consumer product safety commission, which as first passed the Senate in 1972 created a Food, Drug and Consumer Product Safety Agency.

This approach has the advantage of bringing together programs and personnel with similar goals to create a coherent safety framework and team. It may offer an opportunity to reduce administrative and personnel costs.

It is obvious to the Safe Food Coalition that USDA has not successfully balanced its conflicting interests. As the woeful progress on rapid on-line tests, traceback systems, safe handling labels, and other components of a science-based meat and poultry inspection system indicate, all too often agribusiness interests or sheer ineptitude have prevented the Department from protecting public health. It is time for USDA to demonstrate a strong commitment to its consumer constituency or for the U.S. Congress to move USDA's food safety duties to an agency with a proven interest in safeguarding consumers.

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February 2, 1993

MEMORANDUM

To: Pamela Gilbert, Director
Public Citizen Congress Watch

From: David C. Vladeck

Re: Comments on January 22, 1993 Cross Memorandum
On the Outbreak of E. coli 0157:H7 in Washington State

You requested that I review a January 22, 1993 memorandum from H. Russell Cross, Administrator, Food, Safety and Inspection Service, Department of Agriculture, which deals with the outbreak of E. coli contamination in Washington State. More specifically, you asked my opinion about Dr. Cross's discussion of the ramifications of American Public Health Association v. Butz, 511 F.2d 331 (D.C. Cir. 1974)("APHA"). Dr. Cross's memorandum asserts that the APHA court held that "the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation," and that "Congress did not intend the prescribed official inspection legends on meat and poultry products to import a finding that the products were free from salmonellae and other bacteria in that Congress did not intend that inspections include 'microscopic examinations.'" Cross Memorandum, at 1.

Having carefully reviewed the Court's opinion in the APHA case, and based on my knowledge and experience in this area, I am concerned that Dr. Cross's memorandum may be construed to suggest that the APHA ruling (a) disables the USDA from using microscopic and other modes of analysis to determine the extent of salmonellae and bacterial contamination in meat and poultry and from setting microbial standards for raw meat and poultry, and (b) the presence of a rare bacterial strain in meat or poultry does not render the food product adulterated.

Neither of these conclusions is warranted. The APHA case does not suggest that the USDA may not perform whatever technical analysis it believes is warranted to detect salmonellae and bacterial contamination. Nor does it forbid the USDA from concluding that meat or poultry contaminated with a rare or dangerous bacteria, or containing an infective dose level of

bacteria, is adulterated. What is more, the opinion certainly leaves the USDA free to do what we have advocated for years: to set standards limiting the concentrations and strains of bacteria that may be present in meat and poultry products -- standards, which, if exceeded, automatically render the food product adulterated.

In order to place the APHA ruling in its proper context, it is useful to focus on the underlying issues in that case. APHA was a labelling case, not a challenge to USDA's inspection practices. The plaintiffs in the APHA case alleged that the official USDA labels that stated that the meat and poultry was "U.S. inspected" or "inspected for wholesomeness" might constitute misbranding, because the labels failed to adequately explain to the consumer that the product may contain organisms capable of causing food poisoning or infection which would multiply unless the product is properly handled and cooked. The plaintiffs also argued that the labels should contain proper instructions on how to minimize such risks. Both the Meat and Poultry Acts prohibit misbranding.

In addressing the plaintiffs' claim that the absence of a warning about the danger of salmonellae rendered the product misbranded, the Court focused on whether the presence of salmonellae and other bacteria made the product "adulterated" under the Meat and Poultry Acts. To answer that question, the Court examined the definition of adulteration, which is common to both Acts, and which defines the term as covering poisonous, deleterious or harmful additives and filthy or decomposed substances. A product is not considered "adulterated," however, if the deleterious substance does not "ordinarily" render the food product injurious to health.

The Court found that the presence of salmonellae in meat or poultry does not necessarily make them adulterated per se for two reasons. First, the Court suggested, but did not hold, that the adulteration provision did not apply to substances such as salmonella which may be inherent in the meat or poultry. Second, the Court noted that, if proper food handling and preparation procedures are followed, salmonellae does not "ordinarily" render food injurious to health. In reaching this conclusion, the Court credited the Agriculture Department's claim that "the American consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness." APHA, 511 F.2d at 334. The Court also pointed out that the presence of salmonellae or other bacteria can be detected only by microscopic examination. The Court noted, as the plaintiffs conceded, that it would be physically impossible for inspectors to perform microscopic examinations for each of the 10,000 birds poultry

inspectors might examine each day.[1]

Given the narrow focus on the APHA decision, the implication in Dr. Cross's memorandum goes well beyond either the holding or dictum of the Court's ruling. To be sure, the Court recognized that the USDA could not be required to perform microscopic examinations on every single bird or every piece of beef inspected. However, nothing in the Court's opinion closes the door on substantial efforts by the agency to use microscopic, and any other technical tools that might be available to it, to detect salmonellae or bacteria in food products. Indeed, consumer organizations have long advocated that USDA step up its monitoring activities.

Nor did the Court hold that salmonellae or bacterial contamination could never make a food product adulterated. Surely, if USDA inspectors detected the presence of salmonellae or E. coli in concentrations or in strains that would ordinarily render the food product injurious to public health, then the product could be subject to the adulteration provisions of both the Meat and Poultry Acts. Equally important, the Court's opinion leaves USDA free to determine the amount of bacteria that would constitute an infective dose and would accordingly render it injurious to health -- and thus subject to the Meat and Poultry Act's adulteration provisions. Finally, nothing in the opinion casts the slightest doubt on USDA authority to set standards restricting bacterial contamination, which, if exceeded, would automatically render a food product adulterated.

To place this discussion in the context of the outbreak of foodborne contamination in Washington State, there are a few basic points. To begin with, there is simply no reason why the USDA inspectors at the Vons Meat Company plant that packed the Jack-in-the-Box hamburger could not have pulled out samples to analyze by microscopic and other technical means. Dr. Cross's memorandum appears to suggest that such testing is not ordinarily performed. Cross Memorandum, at 2. If that is the case, the USDA's lack of vigilance is regrettable. Nonetheless, had such testing occurred, it is possible that this particularly dangerous strain of E. coli would have been identified. In that event, the USDA would have had the opportunity to consider whether meat containing this rare

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[1] Judge Robinson dissented from this aspect of the Court's ruling, and would have remanded the plaintiffs' claim for a trial. Judge Robinson found that the idea that most consumers are knowledgeable about the risks posed by salmonellae and other bacteria "is a debatable proposition," and noted that the record "contains fact supporting appellants' assertion that people are not generally aware of the danger of salmonellae, much less of the safeguards required to avoid salmonellosis." APHA, 511 F.2d at 336 (Robinson, J., dissenting).

strain of E. coli is adulterated under the Meat Act, in that it presents an unreasonable risk to health, particularly since, insofar as I am aware, meat must be cooked at a very high temperature for an unusually long period of time to destroy the bacteria. Had USDA proceeded in this manner, perhaps this public health crisis could have been averted.

If you have any further questions, please let me know.

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February 4, 1993

BY HAND

Ms. Carol Tucker Foreman
Safe Food Coalition
c/o Foreman & Heidepriem
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Dear Carol:

In the wake of the recent food poisoning tragedy involving USDA-inspected meat products in the state of Washington, questions have again arisen as to the authority of USDA to promulgate standards with respect to bacterial contamination of raw meat and poultry and to treat meat and poultry that fail to meet those standards as adulterated. Specifically, the argument continues to be made that a 1974 decision by the U.S. Court of Appeals for the D.C. Circuit in American Public Health Association (APHA) v. Butz, 511 F.2d 331, stands as a legal barrier to USDA treating bacterially-contaminated meat and poultry as adulterated within the meaning of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

You have asked whether the APHA decision in fact precludes USDA from establishing standards for bacterial contamination and finding noncomplying meat and poultry to be adulterated within the meaning of the FMIA and PPIA. For the reasons discussed below, I conclude that it does not. USDA is free, on appropriate factual findings, to determine that meat or poultry that does not meet standards limiting the amount of harmful bacteria present in the meat or poultry is adulterated within the meaning of the statutes and therefore may not lawfully be sold.

Under Section 1(m)(1) of the FMIA, 21 U.S.C. § 601(m)(1), meat is adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance,

such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health." Section 4(g)(1) of the PPIA, 21 U.S.C. § 453(g)(1), contains the same definition.

The APHA case did not involve the issue of adulteration as such, but rather the question whether, given the risk of bacterial contamination, meat and poultry should be deemed misbranded under the FMIA and the PPIA unless labeled with warnings to consumers about the possible presence of bacteria and directions for cooking and handling to assure safe use. A closely-divided court[1] held that regardless of whether bacterial contamination were viewed as rendering raw meat or poultry adulterated, USDA could reasonably conclude that the meat or poultry was not misbranded, even in the absence of any warning or directions for use. The court upheld USDA's exercise of discretion to determine that a general consumer education campaign was preferable to a labeling requirement.

To be sure, the court did state that "we think that the presence of salmonellae in meat does not constitute adulteration within this definition." 511 F.2d at 334. The court apparently accepted the Department's reasoning that because consumers are generally aware that proper handling and cooking of raw meat and poultry will eliminate the risk of illness from salmonella, the bacteria, as a naturally occurring contaminant, should not be regarded as "ordinarily" rendering the meat or poultry injurious to health. The court assumed that salmonella was an "inherent" contaminant subject to the more-difficult-to-show test of "ordinarily" rendering the product injurious to health rather than an "added substance" subject to the "may render" test.

A few years later, however, the same court of appeals characterized these statements about adulteration in APHA as dictum. Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38, 41 (D.C. Cir. 1982). There the court, applying a similar definition of "adulteration" in the Food, Drug, and Cosmetic Act, found that the APHA decision did not preclude FDA from treating salmonella as a substance that was "added" to shrimp and finding the salmonella-contaminated shrimp to be adulterated. See also Seabrook National Foods, Inc. v. Harris, 501 F Supp. 1086, 1092 (D.D.C. 1980).

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[1] The court was divided 2-1; Judge Robinson dissented, and was joined by two other judges (Bazelon and Wright) in voting for rehearing en banc. While rehearing was denied, Judge Leventhal, as discussed below, emphasized his view that USDA could take action if factual developments warranted.

In any event, the APHA court's statements with respect to adulteration were based on its acceptance of the factual premises of the Department at that time (more than 18 years ago) -- factual premises relating to the state of knowledge of American consumers about proper methods of preparing and cooking food. The court may also have been influenced by the unavailability of practical methods for detecting the presence of bacteria during the inspection process. Nothing in the APHA decision suggests that USDA is not free, upon appropriate findings, to conclude that the human health risk presented by the presence of bacteria in raw meat and poultry is sufficiently serious to render such products "ordinarily injurious to health."[**] USDA, as the expert agency charged with administration of the FMIA and the PPIA, may take into account, for example, evidence that significant numbers of consumers are unaware of the cooking and handling precautions necessary to avoid the risk of illness; that such precautions are in any event often not followed (e.g., when the restaurant customer orders his hamburger "rare"); that the presence of bacteria is more common than previously thought; or that the ability to detect their presence has improved. Indeed, Judge Leventhal, in an opinion explaining his vote to deny rehearing en banc of the APHA decision, expressed his doubts about the Department's ability to educate consumers and cautioned that the court's decision did not "preclude a new challenge if it develops that consumer education programs prove inadequate to provide realistic protection." 511 F.2d at 338.

In short, the APHA decision stands at most for the proposition that USDA, on the factual record as it existed in 1974, was not required by the statute to treat bacterially-contaminated meat and poultry as adulterated. The decision in no way limits the Department's authority, upon appropriate findings,

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[**] Nor does the decision preclude USDA from concluding, if there is a factual basis for such a finding, that there is sufficient human intervention in the process that leads to E-Coli or other bacterial contamination to treat such bacteria as "added substances." If USDA so found, a conclusion of adulteration would readily follow. For there can be little doubt that significant amounts of E-Coli "may render" the meat or poultry "injurious to health."

to establish standards for bacterial contamination and to treat products not meeting those standards as adulterated.

Please let me know if you have additional questions.

Sincerely,

Daniel Marcus

Daniel Marcus

MIKE CHABOT
BILL HALL
FROM: DELL ALLEN

RE: ZERO TOLERANCE INTREPRETATION PROBLEM WITH USDA

I VISITED THIS P.M. WITH RUSSELL CROSS AND ALSO WITH DR. NELSON OUT OF THE DALLAS OFFICE. BASICALLY WHAT WAS SAID BY BOTH PARTIES WAS THAT THEY WANTED A SIMILAR ADMINISTRATION OF THIS MOVE BY ALL PARTIES. I SHARED WITH THEM THE DIS-SIMILARITY OF THE CURRENT INTREPRETATION AS IT IS BEING ADMINISTERED. RUSSELL ASKED ME TO CONTACT DR. NELSON IN DALLAS WHICH I DID. HE ALSO SAID THAT ANYTHING THAT HAPPENED THAT APPEARED TO BE A KNEE-JERK REACTION BY AN IN-PLANT AND/OR CIRCUIT SUPERVISOR SHOULD BE REPORTED IMMEDIATELY TO THE REGIONAL OFFICE. FOR EVERYONE EXCEPT FORT MORGAN AND STERLING THAT WILL BE DALLAS, DR. NELSON, PHONE 214-767-9116. AT FORT MORGAN AND STERLING, THAT IS ALAMEDA, CA., AND I DON'T KNOW THE NAME THERE OF THE DIR. OF THE WESTERN REGION.

KEY POINTS:

1. THE ZERO TOLERANCE IS FOR "OBVIOUS" FECAL AND INGESTA CONTAMINATION. IF THE SPECKS ARE NOT OBVIOUS FECAL AND/OR INGESTA THEN THE NORMAL AQL STANDARDS APPLY. THUS, IF THE INSPECTORS ARE CALLING NON-OBVIOUS SPECKS, THEY NEED TO BE CHALLENGED AS TO HOW THEY KNOW IT IS FECAL AND/OR INGESTA.

2. THEY HAVE BEEN TOLD TO ROAM THE HOT-BOXES AND/OR COOLER AND IF ANY "OBVIOUS" FECAL AND/OR INGESTA CONTAMINATION IS FOUND, THE LOT THAT THAT CARCASS WAS IN SHOULD BE TAGGED AND CHECKED.

3. HEADS ARE TO BE TREATED IN THE SAME MANNER THAT THEY HAVE BEEN TREATED AND THE CONTAMINATION AGAIN MUST BE "OBVIOUS" FECAL AND/OR INGESTA. THE HEAD ISSUE IS A LITTLE LESS CLEAR THAN THE CARCASS ONE IN THEIR MINDS AND I THINK THEY HAD NOT THOUGHT IT THROUGH AS WELL AS THE CARCASS ONE. ONE VIEW IS THAT THE "OBVIOUS" FECAL AND/OR INGESTA CONTAMINATION SHOULD ONLY BE EVALUATED AFTER BONING, ANOTHER WAS LESS CLEAR.

IN BOTH CASES, THE MESSAGE FROM DR. NELSON AND RUSSELL WAS THE SAME. BOTH SAID TO IMMEDIATELY CALL THE REGIONAL DIRECTOR IF THERE SEEMS TO BE AN UN-FAIR AND/OR UN-USUALLY SEVERE INTREPRETATION OF THIS ACTION.

DR. NELSON ALSO TOLD ME THAT THE LETTER THAT WENT OUT OF TOPEKA HAD BEEN CALLED BACK AND SHOULD NOT HAVE BEEN SENT. HE DID NOT NAME THE TOPEKA OFFICE BUT I TOLD HIM THAT I HAD A COPY OF THE LETTER. I ALSO TOLD HIM THAT AT THIS TIME THE TOPEKA OFFICE'S ADMINISTRATION OF THIS WAS DEFINITELY DIFFERENT AT THIS TIME.

PLEASE KEEP US INFORMED AND IT WOULD NOT HURT TO PROVIDE ME WITH NAMES OF INSPECTORS WHO SEEM TO GET OUT OF LINE ON THIS.

I HAVE TALKED TO BOTH LOCHNER OF IBP AND CLAYTON OF MONFORT AND THEY ARE BOTH HAVING MAJOR PROBLEMS IN SOUTHWEST KANSAS IN MARR'S CIRCUIT.

CC: DICK LANN
GREG PAGE
LARRY BINGER
TOM MEYER
DALLEN" XL00 1737

Where's the Beef Been?

Thought Jack in the Box's patties were half-baked? Look at the administration's plan to clean up meat inspection

by Ann O'Hanlon

About the last thing the beef industry needed was an outbreak of killer hamburgers. After all, meat producers have had their fill of bad news in recent years: Scientists churning out more and more evidence that beef fat not only plumps up your girth, but also your cholesterol level; the average amount of beef consumed by Americans dropping 10 percent since 1983; even environmentalists complaining that ranchers have been cutting down too many trees to create grazeland for their herds.

So earlier this year, when a Washington State Jack in the Box served up tainted, not-quite-cooked meat patties, the industry's woes got a whole lot worse. It wasn't just that bovines might devour the planet's forestland in 200 years, or that too many Big Macs will kill you in 20, but that eating the wrong burger might kill you tonight. If federal meat inspection is so lax that spoiled meat could make it all the way to a restaurant table, what's to prevent similar bacterial outbreaks from occurring at any neighborhood burger joint?

That was one public sentiment the war-room Clintonites couldn't miss. So, to their credit, they wasted little time in the weeks following the tragedy to demonstrate that they would prevent future Jack in the Boxes. The solution, announced by Secretary of Agriculture Mike Espy late this winter, was twofold: 160 more federal meat inspectors and a new standard to test raw meat for dangerous disease-causing microbes like E. coli 0157:H7. The plan was right on target—so on target that the media immediately trumpeted the good news on front pages and editorial columns as the long-overdue enactment of crucial reforms. Or so it seemed.

What the media ignored in their eagerness to declare the problem solved was that while Espy and his meat watchers were mouthing the right words, they offered little in the way of a coherent plan. A close read of Espy's "Pathogen Reduction Program" reveals a document so short on substance that it is virtually meaningless. The plan, laments Carol Tucker Foreman, assistant secretary in charge of meat inspection in the Carter administration and now a member of the Safe Food Coalition, is the equivalent of "rearranging the deck chairs on the Titanic."

But the Clinton administration isn't the first to repackage the meat rules and declare a breakthrough. In fact, the current pattern of

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"reform," judging from similar outbreaks in recent years, is the rule rather than the exception: Tainted meat enters the food supply; the government announces a tougher inspection plan; the media applaud; the new plan is never properly implemented—and the issue is forgotten until the next rash of deaths whereupon the cycle begins anew. There is, however, one difference this time around: Unlike the leadership of the past 12 years, this administration is supposed to be giving us more than government as usual.

Steer clear

Of course, the administration can be active in only so many areas, but it's hard to argue that meat inspection doesn't qualify as one of them. Six to eight million cases of foodborne illness occur in the United States annually, and nearly 9,000 result in death, according to the Centers for Disease Control. And of these deaths, more than 80 percent can be traced to consumption of meat and poultry. So inadequate is the meat inspection system that those who know it best barely trust it: "Yes, I eat meat," confesses one Montana meat inspector, "but I shoot my own." Another inspector says that while he does eat store-bought meat, he makes sure to conduct his own personal inspection for hair, ingesta, pieces of metal, and other surprises.

The most dangerous surprises, of course, are the ones you can't see: disease-spreading bacteria. While all meat that passes through processing plants is examined for obvious defects— carcasses defiled by feces, pus-filled abscesses, blood, hair, and the like—there's no requirement that meat be inspected for the little bugs that can kill. Inspecting for these microbes—which means augmenting human observation with equipment capable of detecting the bacteria that cause food-borne disease—means identifying contamination before meat is packed onto delivery trucks. The process involves swabbing the meat or sending a piece for lab analysis, thereby providing the plant and USDA with information on contamination, such as which bacteria are present and to what extent.

Certainly, the notion of testing for microbes is neither new nor part of a fringe-group agenda. As far back as 1985, for example, the National Academy of Sciences (NAS) issued a report recommending sweeping changes in the inspection system, reforms which included a call for microbial testing. And then, like now, change appeared imminent. "We hurried to finish the report," recalls Norman Heidlebaugh, a member of the NAS committee. "We felt a sense of urgency. We thought our recommendations were going to be implemented."

Heidlebaugh's optimism was natural considering the unique combination of characteristics of this public health problem: It's big, and it's solvable. It's tough to say just how much that 9,000-dead-bodies-a-year figure would decrease with an improved system, primarily because lower disease rates would depend on what USDA deemed "permissible contamination" and how strictly it enforced that contamination standard. But putting microbial testing itself into place is the precursor to those other important regulations.

So when the White House made mouth motions about such seemingly smart policy, the press eagerly jumped on board. *The New York Times*, for example, reported that the USDA's new program would enlist "advanced scientific techniques and monitoring equipment to discover invisible and very dangerous microbes," and would "completely change the basis for safeguarding the meat supply." *The Washington Post* concurred: "The U.S. Department of Agriculture is declaring 'war on pathogens,' and its instruments of destruction will include the weapons of technology, infiltration, and information gathering."

The reality? The plan not only ignores any explanation of how the agency plans to fund microbial testing, but fails to even lay out what level of microbial infection in meat should cause inspectors to sound alarms. And those are just the obvious omissions. The plan, explains Dave Carney, veteran meat and poultry inspector and president of the North Central Council of Food Inspection Locals, is so toothless that it offers "no penalties for violations, it has no role for inspectors, and no pathogen is discussed in any detail."

Instead, the report, in the finest Washington tradition of water treading, promises studies and research toward better equipment. Out of 29 pages, nine are appendices and four detail a public and merchant education campaign—both rel-

evant perhaps, but not what should make up half of a "program."

While the USDA has made good in one area of reform—hiring 160 more inspectors—that fix is little help without other changes: More inspectors simply means more people contending with inadequate contamination standards and plant conditions. "If something's gone wrong," explains Heidlebaugh, who is also a retired professor of veterinary public health at Texas A&M University, "don't intensify what you're doing."

But that's exactly what's likely to happen. The USDA is not opposed to a safer meat supply, of course, but once you get beyond its public posturing on microbial testing, agency officials aren't all that committed to making the reforms stick. Why not?

Recently Russell Cross, the chief of USDA's meat inspection division, claimed while testifying before Congress that microbes such as E. coli can be detected only through a six day test. While all microbes cannot be detected immediately, Cross failed to mention that scientists in his own agency, namely at a USDA lab in Philadelphia, are using a 24-hour test to detect the dangerous E. coli, as well as 48-hour tests to spot Listeria and Salmonella.

USDA bureaucrats, when questioned, also downplay microbial testing, arguing that analyzing every carcass would be impossible. That's true, of course. But who said every carcass should be tested? Spot-testing carcasses is not a leakproof safety net, but non-USDA food safety experts say it would go a long way toward bringing some semblance of control. Indeed, one inspection program heralded by USDA and others is the Hazard Analysis Critical Control Point system, or HACCP. The awkward appellation simply means that there are a few, and only a few, points in the inspection process which are critical for quality control. If such "hot spots" can be determined, then spot testing at those points would provide extensive data on contamination.

Perhaps the only USDA excuse that carries any weight is the cost of the testing. But even here, the agency's estimates reveal more of a reluctance to tackle the problem than a willingness to see it dealt with effectively. USDA estimates that "adequate" testing will cost nearly $58 billion. Simply stated, says Ed Zadjura, assistant director of food safety at the General Accounting Office and co-author of a number of GAO reports on meat inspection, "that number is totally, absolutely meaningless. Nobody who has advocated bringing this system into the 20th century has advocated checking every piece of meat, which is what that figure must be based on. I think it's just a scare tactic." The budget office of USDA reports that it was instructed to calculate the figure based on a 20 percent sampling rate at $50 a test. Zadjura's counterpoint, once informed of the agency's math: Less than 1 percent would need to be sampled and $50 sounds suspiciously high. Suffice it to say that no outside agency has estimated what the program would cost, and USDA doesn't seem to want them to.

What USDA may really find repulsive about microbial testing, however, probably has less to do with limits of science or money than with simple bureaucratic cowardice. That is, USDA is shrewd enough to realize that if it is officially responsible for finding deadly microbes—admittedly no easy task—then it will be the USDA, and not the local burger kitchen, that will be under the gun the next time people die from tainted meat or poultry.

Fortunately, there is a government body that can make USDA take microbe testing seriously: Congress. Unfortunately, the legislature isn't likely to amend current inspection laws anytime soon, thanks to the usual combination of industry money and Congressional gridlock.

Meat and poultry industry PACs dug up $30,000 to donate to the 1992 re-election campaign of Rep. Charles Stenholm, who happens to be from Texas cattle country and who also happens to chair the agricultural subcommittee with jurisdiction over meat inspection. (Stenholm's $30,000 in meat and poultry PAC money, by the way, was $13,000 more than his opponent collected in total campaign contributions). Stenholm also accepted almost $9,000 in 1990 in meat industry honoraria, and took nine trips that year sponsored by meat and poultry interests.

Meat is mortar

It hardly needs to be said that revamping meat inspection laws would not endear Stenholm to the meat industry, which is an outright enemy of any governmental standards for microbial contamina-

tion. That should come as little surprise considering what testing will mean, at least in the short run—lost revenue. Not only would it add another step to the processing line, but comprehensive testing would ultimately mean discarding larger quantities of meat than are now rejected using the eyeballing inspection methods.

Nonetheless, some larger meat companies *do* test for microbial contamination at their own on-site labs, mainly because some buyers, such as McDonalds, insist upon it. Is it cost effective? Just ask Jack in the Box. Government intervention would help small companies, who can't afford in-house labs (or big PAC contributions), and therefore aren't competitors in the McDonalds league.

Touch and go: The USDA's answer to microbial testing.

A favorite Stenholm line is to cite the very real problem of divided jurisdiction—USDA is in charge of meat and poultry, FDA in charge of seafood and most other foods—and say the whole system should be scrapped and begun anew. This, of course, is a prescription for stasis.

According to an aide, Stenholm is not without a plan: more studies. Stenholm recently asked the General Accounting Office to take yet another look at testing. His office eagerly awaits the results, which are due out this fall. And, the aide added, Stenholm—in his zeal to get to the heart of the matter—may request yet another in-depth review of meat inspection, this time from the National Academy of Sciences. When reminded that NAS executed such a study eight years ago and that its recommendations are still not law, the aide blamed labor unions for resisting the proposed changes, but later acknowledged that there was some industry pressure as well.

The labor union charge rings, well, a little off-key. The United Food and Commercial Workers (UFCW), one of the unions representing plant workers and inspectors, endorses all changes recommended by NAS and has done so since the report was published. The American Federation of Government Employees (AFGE), the other major union, proposed an amended list of changes for the inspection program because it felt that the NAS proposals were couched in language that could provide USDA with escape routes from meaningful change. With hindsight, that seems a justifiable concern.

While Congress is busy awaiting reports, the last remaining avenue to prod reform might appear to be the courts, e.g. a class action suit by the infected masses against USDA. Forget it—it's been tried. In 1974, the American Public Health Association took Earl Butz, the secretary of Agriculture, to court, charging USDA with misleading consumers by putting the label "U.S. Inspected for Wholesomeness" on a product that could make you sick. The court ruled that microscopic examination was the only method of determining whether meat was "adulterated," and that microscopic inspection was not required under current meat inspection law. Which brings us back to changing the law and the politics of Charlie Stenholm.

All of this simply throws the ball back where it should be—in the executive's court. The Clinton administration may not be able to predict with any certainty, say, the course of the nation's economic future or where the next international bloodbath will occur, but one safe bet is that sooner or later, there's going to be another rash of deaths from tainted meat. Now that there's technology to help prevent it, what's missing is the political will. It would be satisfying if the man who gave a White House blessing to fast food were the same man who made the stuff safer to eat. □

Courtesy of AFGE

Seattle Post Intelligencer (10/29/93)

Critics knock meat inspection proposal on checks for feces

By Christopher Hasson
P-I Washington Correspondent

WASHINGTON — A federal food safety agency is circulating a proposal that critics say could result in federal inspectors checking less than 1 percent of carcasses for fecal contamination at many of the nation's meat plants.

The draft directive by the Agriculture Department's Food Safety Inspection Service would let private plant employees, not federal inspectors, select meat samples to check for feces, which often get on meat during slaughter and can carry dangerous bacteria.

Agriculture Secretary Mike Espy announced eight months ago that he would strictly enforce a policy of "zero tolerance" for beef tainted with feces in federally inspected plants. He told the inspection service to come up with a set of detailed rules to help implement that policy, leading to the draft directive.

Tom Devine of the Government Accountability Project, which represents USDA whistleblowers, said the rules reflect industry lobbying and amount to an "honor system" and "sham reform."

Espy spokeswoman Mary Dixon said Espy and top aides had not yet seen the document, although congressional staffs already have been briefed on it and

See MEAT, Page A6

Seattle Post Intelligencer (10/29/93)

Meat: Consumer comments on proposal welcome

From Page 1

copies have been sent to consumer groups and industry officials for their comments. Dixon stressed it was a draft — "so tentative . . . nothing is set in stone" — and that consumer comments are welcome.

She said Espy was pushing hard on the clean beef campaign. He has set up a special team to make spot checks on beef plants.

USDA officials say feces, milk and ingesta can carry dangerous bacteria such as the E. coli 0157:H7 that killed three children and sickened about 500 people in Washington state last January. There have been other E. coli cases since then.

Espy has invested much personal capital in a safe food campaign. But he has had some embarrassments, most recently when federal courts blocked his program for safe handling labels on ground meat. Some officials suggest Espy's team is frustrated by a less than gung-ho attitude in the Food Safety Inspection Service, with its carryovers from the Bush administration.

Inspection service officials discussed the draft directive with committee staff in Congress last Friday and Monday.

Jim Hodges of the American Meat Institute, an industry group, says the proposed rules are "stringent" and "burdensome."

But consumer lobbyists say the regulations would step back from stringent enforcement in several ways:

■ Yielding responsibility. Plant workers would be responsible for selecting random carcass samples for testing, for testing samples, and for notifying federal inspectors of contamination.

Commenting to the USDA on such proposed delegation of authority, Safe Tables Our Priority, an organization of friends and family of E. coli victims, said it would simply be "an enhancement of . . . industry control over the inspection process."

Industry officials say the rules would be tough because federal inspectors would approve plant safety plans and would make spot checks of the safety system. If plant employees found dirty beef, management would be required to bring in more employees to check all carcasses. Federal inspectors could reduce speed of the slaughter line by 10 percent.

■ Small samples. Under the draft directive, plant employees would select three, "sample units," a unit being half a beef carcass, for inspection each hour, Devine said.

Federal inspectors would monitor this sampling at least once every four hours. If a plant processed 300 carcasses an hour or 1,200 every four hours, this would mean a federal inspector could monitor the sampling of less than 1 percent, Devine said.

Line speeds vary. Many are slower than 300 an hour. But in all of them, a small percentage of carcasses would be double checked, Devine said.

An Espy aide, who asked not to be named, acknowledged that the proposed small samples could be a concern to consumers and urged them to send suggestions.

■ Timing of inspections. Consumer groups say the directive is a retreat by the agency on the important question of when carcasses should be sampled.

A memo last March by R.D. Kelly, Topeka-area supervisor for the inspection service, instructed plant inspectors to monitor carcasses for feces before they are washed and sprayed. One reason, says federal inspector and safety advocate Steve Cockerham, is that spraying scatters feces in tiny pieces that are harder to detect.

Kelly's memo, which had applied only to Midwest plants, was rescinded after industry groups protested that it wasn't applied uniformly nationwide.

The latest draft regulations do not require inspectors to check carcasses for feces prior to the spraying, Devine said. The draft rules say samples should be examined "after carcass evisceration, but before the cooler."

That would allow the plants to perform the inspections after the carcasses have been sprayed and could result in the spread, rather than the control, of fecal contamination, Devine said.

But Gary Wilson of the National Cattleman's Association said delaying inspections until after spraying would not pose a risk. Spraying might be more hygienic than trimming feces, because the trimmer's knife or hands could spread bacteria, he said.

■ Poultry. Espy has said he wants to extend "zero tolerance" to poultry. But there is no sign the USDA is close to doing this. The draft directive makes no mention of poultry.

Without detailed rules, inspectors have been enforcing a vague "zero tolerance" in beef plants but interest groups agree results are inconsistent. Hedges complains the USDA is unclear what it means by "zero tolerance."

Carol Foreman, an ex-USDA food safety official now with Safe Food Coalition, said the USDA had been too slow with regulations.

Last summer, Espy ordered special spot inspections in meat plants across the country. About 30 had to be shut down temporarily due to unsanitary conditions, many involving meat tainted with feces, despite the "zero tolerance" initiative.

Cockerham provided documents showing that in late July a Nebraska plant received two large shipments of beef that were smeared with feces from a slaughter house in Wisconsin, even though they had passed federal inspection in Wisconsin. Nebraska inspectors trimmed more than 1,100 pounds of tainted meat from those shipments, he said.

USDA officials say they are serious about zero tolerance. Dixon said the team conducting spot meat plant inspections, based in Lawrence, Kan., was having positive results, but declined to be specific.

"As we improve the system, we hope to get better trained inspectors. The system has been neglected," she said. She said Espy appointed a special Washington, D.C., liaison to listen to meat inspectors' enforcement complaints, came up with a plan to give problem plants special scrutiny, and added 200 meat inspectors. She said Espy had done more on food safety in 10 months than others had in decades.

Mr. TOWNS. Dr. Walker.

STATEMENT OF BAILUS WALKER, JR., Ph.D., M.P.H., PROFESSOR AND DEAN, COLLEGE OF PUBLIC HEALTH, UNIVERSITY OF OKLAHOMA HEALTH SCIENCES CENTER, ON BEHALF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION

Dr. WALKER. Thank you, Mr. Chairman. I am Bailus Walker, professor of environmental Health at the University of Oklahoma Health Sciences Center and a past president of the American Public Health Association.

I appear here today on behalf of the Association, the world's oldest and largest organization of health professionals. From its inception, we have had as one of our major objectives the prevention of disease and dysfunction and premature death. It was our Association that held the first National Food Protection Conference back in 1977 and, as you see from the data that Ms. Foreman has prepared, we have filed a lawsuit against the Department of Agriculture back in 1974 on issues of food safety.

We believe that the best approach to preventing disease and dysfunction is to focus on whole communities as compared to one-on-one medicine.

We also recognized that food safety is a serious problem and it has been clearly articulated by persons who preceded us, including representatives from the Centers for Disease Control who have sketched in fairly broad strokes the nature of the public health problem.

I think it is very clear that over the past 20 years, our knowledge of microorganisms which may increase the risk of foodborne disease has increased substantially, and it is also very clear that the potential for food to be involved in microbial threats to human populations is very great. This is due in large part to the many points in the food chain at which food safety can be compromised.

Our food protection system is fragmented, complicated, and confused, involving as it does multiple Federal, State, and local governmental agencies, regulations, codes and ordinances. This has been widely discussed, and I certainly won't repeat it here, except to point out that the situation is exacerbated by the retention of the meat and poultry inspection responsibilities in the U.S. Department of Agriculture and by the obvious concerns of the Department of Health and Human Services for all matters dealing with the salubrity of food.

Thus, in the past several years we have seen a number of reports by both lay and professional groups which have identified the weaknesses in the USDA food monitoring and surveillance system. And the common theme here has been the failure of the Department of Agriculture to adequately monitor the food supply. The Institute of Medicine report has been referred to. The National Academy of Sciences report has been referred to. Both make it clear that there is a serious problem.

Having said that, we would not argue with the view that food safety laws have, without a doubt, improved the quality of food in the United States, but even to the most casual observer, it is evident that the system is in disarray and most obvious is the division of responsibility between USDA, an agency whose mandate is to

promote the welfare of American farmers and promote the sale of agricultural products, and the Department of Health and Human Services whose primary focus is protecting the health through the application of prevention strategies.

Not so obvious to the public is the lack of modern-based approaches to controlling and eliminating microbial contamination in meat and poultry. To be sure, the prevention of foodborne disease requires something more than a simple, random, visual inspection of meat and poultry as done by the USDA. It must include modern microbiological testing which you have heard about, appropriate training of the inspectional staff and ongoing quality assurance element for the meat inspection program.

The traditional focus on slaughter operations must be expanded to include other potential sources of meat and poultry related hazards such as production and preparation as well as handling at the consumer level.

The use of microbiological risk as a common denominator creates a measurement that would help the USDA distinguish between real serious public health hazards and economic fraud. This microbiological assessment would provide a good guide post of indicating the most promising pathways for preventing foodborne diseases and it would also help the Federal establishment target its resources and mobilize and deploy its expertise in the most efficient way.

The ultimate beneficiary of these changes would be the American consumer.

Let me submit that change in the way the Federal Government does its meat and poultry monitoring and surveillance activities means moving the public health sciences to the very center of the Nation's food protection enterprise, and here the public health expertise could play a very central role, given the role that the epidemiology and biostatistics have played in risk management in the past.

So it was entirely appropriate for the National Performance Review headed by Vice President Gore to recommend that the responsibilities for food safety be consolidated in a single agency. We thoroughly support that recommendation. We believe there is a nucleus in FDA and in the Department of HHS that could be built upon to provide the appropriate scientific base and the expertise necessary to protect the health of the American consumer.

Mr. Chairman, I ask my full statement be inserted in the record.

Mr. TOWNS. Without objection the entire statement will be included in the record.

[The prepared statement of Dr. Walker follows:]

Statement of
BAILUS WALKER, JR., Ph.D., M.P.H., PROFESSOR AND DEAN
COLLEGE OF PUBLIC HEALTH, UNIVERSITY OF OKLAHOMA
HEALTH SCIENCES CENTER
to the
SUBCOMMITTEE ON HUMAN RESOURCES
AND INTERGOVERNMENTAL RELATIONS
of the
COMMITTEE ON GOVERNMENTAL OPERATIONS
UNITED STATES HOUSE OF REPRESENTATIVES
November 4, 1993

Mr. Chairman, I am Bailus Walker, Jr., professor of environmental health and dean of the College of Public Health, University of Oklahoma Health Sciences Center. I am also a past president of the American Public Health Association.

I appear today on behalf of the American Public Health Association (APHA), the world's oldest and largest organization of health professionals. From its "birth", the Association has had as major objectives the prevention of disease, dysfunction and premature deaths. We believe that this can best be accomplished by health and safety measures aimed at a whole community.

In this direction, APHA organized and sponsored the first National Conference on Food Protection which was held in 1977 in Denver. In addition to this and other educational forums on consumer health, the APHA in 1974 pursued legal action against the U.S. Department of Agriculture (American Public Health Association v. Butz, U.S. Court of Appeals for the DC Circuit) on the question of whether, given the risk of bacterial contamination, meat and poultry should be deemed misbranded unless labeled with warnings to consumers.

The consistent programming at the Association's annual meetings of presentations on foodborne diseases bespeaks the importance that our 50,000 members place on this issue. It also bespeaks continuing difficulties in achieving our disease-eradication objective. Thus, we are especially pleased to have this opportunity to address a number of issues related to food safety and to the federal system designed to ensure a safe and wholesome food supply especially meat and poultry.

We thank you, Mr. Chairman, for inviting us. An appropriate starting point for these remarks is to sketch in fairly broad strokes, blurring an infinity of details, the scope of foodborne illness in this country. And here I draw heavily on data developed by our colleagues at the Centers for Disease Control and Prevention in Atlanta, Georgia.

Foodborne infections cause an estimated 6.5 million cases of preventable human disease and 9,000 deaths annually in the United States. In recent years both the total number of individuals affected and number of food poisoning outbreaks have been increasing. Some of these increases may be due to better reporting; nevertheless, food poisoning in the United States is grossly underreported despite the best surveillance efforts of the Centers for Disease Control and Prevention. So, the data available could well be the tip of a large iceberg because most foodborne diseases occur as isolated or sporadic events rather than as part of large dramatic outbreaks that attract the attention and investigatory resources of public health authorities.

Although a foodborne illness can be mild, causing an upset stomach or diarrhea, it also can cause death as was evident in the widespread foodborne bacterial poisoning which was traced to a restaurant chain in the northwestern part of the United States. Still vivid in our memory is the 1987 death of four retarded Utah patients, and the illness among some fifty other residents who consumed contaminated beef in a mental institution. A year later, 32 junior high school students in Minnesota became ill (fever, chills, bloody diarrhea) after consuming precooked frozen hamburger patties served in the school cafeteria. There are other such examples too numerous to recite here.

Over the past 20 years, our knowledge of microorganisms that may increase the risk of foodborne illness has also increased. Indeed it is clear that the potential for food to be involved in microbial threats to human populations is great. This is due in large part to the many points in the food chain at which food safety can be compromised.

These chain of events begin wherever animals are raised; it proceeds through a complex system of processing, distribution and retailing and ends with the use of the food product by the consumer, which is usually a susceptible host because there are not immunizing agents against foodborne illness.

An important component of this increase in understanding is a better scientific grasp of the factors that allow microorganisms to cause human disease. Reversing the upward trend in the incidence in foodborne illness and death necessitates a coordinated and comprehensive effort by various individuals, organizations, industry and government.

In the United States the fragmented, complicated and confused food protection program---involving as it does multiple federal, state and local governmental agencies, regulations, codes and ordinances---has been widely discussed with monotonous regularity and will not be repeated here except to point out that the situation is exacerbated by the retention of meat and poultry inspection responsibilities by the United States' Department of Agriculture (USDA) and by the obvious concern of the Department of Health and Human Services for all matters dealing with the salubrity of foods.

Thus, in the past several years the problems of assuring through the regulatory process a safe supply of meat and poultry have been brought into bolder relief by a number

of professional and lay groups. Weaknesses in the USDA's food monitoring and surveillance program have been the subject of wide-ranging investigations by American journalists. The result of these investigations have been well publicized in major daily newspapers.

My fellow members of the Institute of Medicine of the National Academy of Sciences have also examined and reported on USDA food protection efforts. The central theme of all of these reports is that the USDA has major flaws in its efforts to carry out its mission of assuring healthy food products for consumers.

For example, the Institute of Medicine concluded that the USDA program for monitoring of pathogens and chemical residue in cattle carcasses was not designed to prevent public exposure or eliminate these risks to public health.

Another National Academy of Sciences study of poultry inspections concluded that, "... the present system of continuous inspection provides little opportunity to detect or control the most significant health risk associated with broiler chickens."

Although the information was not sufficient for the Academy's committee to conclude that the USDA inspection program has no public health benefits, the weight of evidence suggested that the program could not provide effective protection against the risks presented by microorganisms that cause disease in humans.

Having said that, we would not argue with the view that the food safety laws have without a doubt improved the quality of the United States' food supply. But even to the most casual observer it is evident that the system is in disarray. Most obvious is the division of responsibilities between the USDA---an agency whose mandate is to promote the welfare of American farmers and promote sales of agricultural products such as meat and poultry---and the Department of Health and Human Services whose primary concern is protecting the health of the public through disease prevention strategies.

Not so obvious is the lack of a modern risk-based approach to controlling and eliminating microbiological contamination in meat and poultry. Indeed the prevention of foodborne disease requires something more than simple random visual inspection of meat and poultry as is now done by the USDA. It must include modern microbiological testing, updated quality assurance elements in meat and poultry inspection, appropriate training and retraining of the inspection work force consistent with developments in science and technology. To be sure, the traditional focus on slaughter operations must be expanded to include other potential sources of meat- and poultry-related hazards such as production and preparation as well as handling. Using microbiological risk as a common denominator creates a measurement that would help USDA distinguish between truly significant public health hazards and economic fraud. It would provide an excellent guidepost for indicating the most promising pathway to preventing foodborne illness provoked by the consumption of contaminated meat or poultry. It would also help the federal government target its resources, mobilize and deploy food protection expertise in an efficient and rational way. The ultimate

beneficiary would be the American people.

Changing the way the federal government does its meat and poultry monitoring and surveillance activities means moving the public health sciences to the very center of the nation's food protection enterprise. Here the public health expertise could play a central role, given the part that such core public health methodologies as epidemiology and biostatistics must play in developing and maintaining appropriate risk assessment capabilities.

In fact, hazard identification and exposure assessment---central components of any formal health-based risk assessment process---have long been core activities for the public health community. Thus, it was entirely appropriate for the National Performance Review headed by Vice President Al Gore to recommend that responsibility for food safety be consolidated into a single agency and that the policy and inspection system be implemented on an objective scientific basis. We fully support that recommendation.

Under the Vice President's recommendation, all food safety responsibilities would be assigned to the Food and Drug Administration (FDA). That agency would handle all food safety regulations and inspections, spanning the work of many different agencies now involved. FDA would develop rigorous, scientifically-based systems for meat and poultry inspections. It would employ modern technology to detect the presence of microorganisms, giving the American public maximum health protection for a given investment of resources. The USDA could then devote more of its energy and resources to the broad range of contemporary economic and social issues impinging on the welfare of American farmers.

Another line of logic seems to run through the Vice President's recommendation and that is prevention---anticipatory action to minimize disease, dysfunction and premature death---a fundamental principle that should permeate the current health care reform discussions. Today a broad spectrum of health, social, and economic factors both single and in combination are bringing a new sense of urgency and seriousness about community-based disease prevention as an essential component of a new health policy.

Almost daily we see evidence that the public expects more from the health/medical services system than treatment of the sick and injured. Indeed if health care reform is to be more than the mere extension of insurance coverage for conventional diagnosis and treatment, and if it is to improve the health status of the American people and control health care cost, prevention must play a prominent role at every level of service.

Also essential is the recognition that prevention of bacterial food poisoning is a resource-intensive process and the vision of a better food safety component of the national health services system cannot become a reality without careful and creative attention to fiscal and human resources.

Finally, our ability to respond to the food safety challenges of today and tomorrow is strongly dependent on the quality of information produced by a well-organized monitoring and surveillance system to accumulate the necessary health-focused data so essential for determining program effectiveness as well as for the establishment of priorities.

We also recognize that assuring a safe food supply requires a new and more effective application of scientific and technological skills. Here FDA and the Department of Health and Human Services have a nucleus upon which to build such a system.

So, as Congress and the Administration move forward with plans to improve the nation's food safety system, we will make available to both branches of the federal government the full complement of intellectual and other resources of the American Public Health Association.

Again, we thank you Mr. Chairman for the opportunity to articulate and to place in the record of this hearing the views of APHA.

Mr. TOWNS. Dr. Crawford.

STATEMENT OF LESTER M. CRAWFORD, D.V.M., Ph.D., EXECUTIVE DIRECTOR, ASSOCIATION OF AMERICAN VETERINARY MEDICAL COLLEGES

Dr. CRAWFORD. Thank you, sir.

As has been mentioned, in 1985, the National Research Council completed a comprehensive study titled "Meat and Poultry Inspection, The Scientific Basis of the Nation's Program."

It made five recommendations that were addressed for the most part by the establishment of a new cadre of personnel in FSIS and also the establishment of the Donald L. Houston Training Center at Texas A and M University, a $2.6 million project, and the establishment of the Pathology Correlation Center at Iowa State University.

After this study, the FSIS asked the National Academy of Sciences to do a similar study which concentrated on poultry. There also emanated five recommendations from that study. The Department then commissioned a multimillion dollar study to be done in an actual poultry plant changing the paradigm for poultry inspection and poultry production, slaughter, and processing. That was completed in 1991 in Puerto Rico and the results of that study are now being applied not only by the industry, but by the Food Safety and Inspection Service.

Surveillance of foods that employ measurements of physical properties, chemical analyses, and microbiological testing are relatively new developments. The primary limitations of an inspection system that would rely only on laboratory analysis include the difficulty of collecting and examining enough samples to obtain meaningful information, the time required to obtain results, and, except for epidemiological purposes, such tests are unacceptably costly.

Mr. Chairman, an analysis of the relevant scientific literature on this subject will reveal that one simply cannot test safety into food. Bad food will remain bad food no matter how many times you test it and how much money you spend testing it. Moreover, nondestructive testing of every container of food offered for sale would in and of itself offer no protection from foodborne disease.

A recent conference held by the European Food Forum in Brussels concluded that even if you tested every container of food, you would have less than a 30 percent chance of finding 95 percent of food contaminated with disease causing organisms.

I believe a risk assessment approach is needed to evaluate health hazards associated with meat and poultry inspection. An effective risk management program will consist of several monitoring activities, some of which are outside FSIS's authority. Therefore, a comprehensive effort to protect the public from foodborne hazards will require an active and consistent liaison between FSIS and other government agencies. Attempts to control these public health risks could be significantly compromised without such interagency cooperation.

The present system of continuous inspection provides little opportunity to detect or control the most significant health risks associated with meat and poultry. There is sufficient evidence to conclude that the current program cannot provide effective protection

against the risks presented by microbial agents pathogenic to humans.

In 1985, the HACCP system was recommended by the National Academy of Sciences in the publication "An Evaluation of the Role of Microbiological Criteria for Food and Food Ingredients." In this report, that subcommittee on microbiological criteria concluded that a preventive system or HACCP was essential for the control of microbiological hazards.

HACCP is a preventive system of quality control which involves systematic studies of the ingredients, the food product, the conditions of processing, handling, storage, packaging, distribution, and consumer use.

In addition to this kind of change which would be a major shift for the agency, I would like to bring your attention to the recent agreement called relationship by objectives [RBO] reached between FSIS management and the 6,500-member food inspectors union. I agree with the agency that the new agreement is necessary to move USDA forward in designing a science-based program to improve public health protection.

The RBO agreement improves communication between management and the union and establishes a framework for labor and management to deal fairly and openly with each other and to respect each others' rights and responsibilities.

Mr. Chairman, food safety inspection systems are currently divided among four government agencies.

Historically, the predecessor food safety agencies—FDA and FSIS—were located in USDA. A consolidated agency should probably be reorganized under the Department of Health and Human Services in order to provide the uniform approach, cost savings, and centralization of authority that is so desirable.

Had there been in 1906 a Department of Health and Human Services, I suspect FDA and the Meat Inspection Program as well as EPA would have been placed there. Now that there is a Health Department, I believe that optimum efficiency and cross-utilization of personnel could be obtained there.

Thank you very much.

Mr. TOWNS. Thank you, Dr. Crawford.

[The prepared statement of Dr. Crawford follows:]

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Statement of

Lester M. Crawford, DVM, PhD

Executive Director
Association of American Veterinary Medical Colleges

Before the
House Government Operations Subcommittee on
Human Resources and Intergovernmental Operations

November 4, 1993

On USDA Progress in Reforming Meat and Poultry Inspection

Mr. Chairman and members of the subcommittee, thank you very much for the opportunity to testify on reinventing the federal food safety system--U.S. Department of Agriculture's (USDA) progress in reforming meat and poultry inspection.

I am Dr. Lester Crawford. From 1986-91, I served at the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture -- four of those years as Administrator. Prior to that, I served as Director of the Center for Veterinary Medicine at the Food and Drug Administration, and in various positions at the University of Georgia including Head, Department of Physiology-Pharmacology.

Currently, I am Executive Director of the Association of American Veterinary Medical Colleges. In this capacity, I manage and coordinate the national affairs of the North American Veterinary Medical Colleges, departments of veterinary science, and the Animal Medical Center as these relate to teaching, research and service missions of the academic veterinary medical community.

When I came to FSIS, the National Research Council had just completed (1985) a comprehensive study titled *"Meat and Poultry Inspection: The Scientific Basis of the Nation's Program."* The principal recommendations of the study were:

- ♦ Use in all phases of inspection a technically qualified team with up-to-date knowledge of veterinary medicine, food and science technology, nutrition, public health, and public management.

- ♦ Development of a list of diseases that can be identified by each step in the inspection procedure to determine whether the steps are useful for protecting human or animal health, useful for detecting aesthetically objectionable conditions, necessary to protect consumers against fraud, or able to provide other identifiable benefits.

- ♦ Random sampling of retained or condemned carcasses and parts of carcasses in order to develop definitive diagnoses can be used to establish baseline data on etiologies associated with each condemnation category and to provide material for pathology correlation sessions as continuing education for in-plant veterinary medical officers.

- ♦ Establishment of a mandatory system of initial and continuing education for inspection personnel that emphasizes food science, food technology, pathology, and public health, combined with a certification program.

- ♦ Establishment of a scientific and technical FSIS staff of respected scientists who play a substantive consultative role in the development of policy.

Subsequent to that report, FSIS asked the Council to undertake a second study to be focused specifically on poultry inspection. *"Poultry Inspection: The Basis for a Risk-Assessment Approach"* recommended the following:

♦ The ongoing search for microbial risks should continue and be complemented by new research. Emphasis should be placed on the prevention of human disease rather than on simple control of microbial counts during slaughter and processing.

♦ Potentially pathogenic microorganisms on poultry should be identified, the potential for exposure to an infectious dose of each pathogen should be determined, and the potential impact on public health that would result from the failure to control exposures should be evaluated.

♦ The critical control points at which known pathogenic microorganisms such as Salmonella and Campylobacter may be introduced into the poultry system should be identified and monitored, preferably as part of an Hazard Analysis Critical Control Point (HACCP) program.

♦ A population-based surveillance program should be established so that disease occurrence can be correlated with inspection strategies. This will require measuring the level of pathogenic microorganisms on market-ready poultry as well as establishing a system for surveillance of disease within a well-defined population.

♦ A range of educational programs for people who raise poultry and for those who handle raw broilers in slaughterhouses, at retail, and during food preparation in the home and commercial establishments should be developed or intensified. As part of this effort, poultry products should be developed or intensified. As part of this effort, poultry products should be labeled at retail to inform consumers how to handle the poultry to prevent diseases originating from microbial contaminants.

Mr. Chairman, I would like to turn your attention to the major components and guiding principles of an optimal federal food safety systems and options for developing and implementing such a system. I strongly recommend, as I did as Administrator of FSIS, that the food safety inspection process shift from organoleptic evaluation to a hazard analysis critical control point system (HACCP).

Surveillance of foods that employs measurements of physical properties, chemical analyses, and microbiological testing are relatively new developments. The primary limitations of an inspection system that would rely only on laboratory analysis include:

1. the difficulty of collecting and examining enough samples to obtain meaningful information;
2. the time required to obtain results (usually several days); and
3. except for epidemiological purposes, such tests are unacceptably costly.

Mr. Chairman, an analysis of the relevant scientific literature on this subject will reveal that one simply cannot "test" safety into food. Bad food will remain bad food no matter how many times you test it and how much money you spend testing it. Moreover, non-destructive testing of

every container of food offered for sale in America would in and of itself offer no protection from food-borne disease. What will prevent food-borne disease is HACCP.

I believe that a risk-assessment approach is needed to evaluate health hazards associated with meat and poultry inspection. An effective risk-management program will consist of several monitoring activities, some of which are outside FSIS's authority. Therefore, a comprehensive effort to protect the public from food-borne hazards will require an active and consistent liaison between FSIS and other government agencies. Attempts to control these public health risks could be significantly compromised without such interagency cooperation.

The present system of continuous inspection provides little opportunity to detect or control the most significant health risks associated with meat and poultry. There is sufficient evidence to conclude that the current program cannot provide effective protection against the risks presented by microbial agents that are pathogenic to humans.

In 1985, the HACCP system was recommended by the National Academy of Sciences (NAS) in the publication *An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients*. In this report the NAS Subcommittee on Microbiological Criteria for Foods and Food Ingredients concluded that a preventive system (HACCP) was essential for control of microbiological hazards.

HACCP is a preventive system of quality control which involves a systematic study of the ingredients, the food product, the conditions of processing, handling, storage, packaging, distribution and consumer use. The HACCP system seeks to identify the hazards associated with any stage of food production, processing, or preparation, assess the related risks, and determine the operations where control procedures will be effective. Thus, control procedures are directed at specific operations that are crucial in ensuring the safety of foods. The system offers a rational approach to the control of microbiological hazards in foods, avoids the many weaknesses inherent in the inspectional approach and circumvents the shortcomings of reliance on microbiological testing.

Drawing on principles used by a number of food-processing companies, HAACP provides guidance on the assessment of risks that occur during the processing, preparation and storage of foods in homes, schools, food service establishments, cottage industries, and street markets.

Unlike most traditional food-inspection activities, the HAACP approach is based on an understanding of the factors that contribute to outbreaks of foodborne disease and on applied research on the ecology, multiplication, and inactivation of foodborne pathogens. Even where data are not available, a hazard analysis can detect potential problems and identify the critical control points of an operation. Thus, food safety agencies can target their resources on the greatest public health risks in an establishment, rather than on general sanitation and superficial improvements.

Mr. Chairman, I would like to also bring your attention to the recent agreement called

Relationship by Objectives (RBO), reached between food safety management and the 6,500 member food inspectors union. I agree that the new agreement is necessary to move the agency forward in designing a science-based program to improve public health protection. The RBO agreement improves communication between management and the union and establishes a framework for labor and management to deal fairly and openly with each other and to respect each other's rights and responsibilities.

New information, new technology, and new health care concerns have severely tested the efficiency and adequacy of the present labor-intensive inspection system. In response to increased public health risks, USDA has had to shift regulatory strategies to improve phases of the inspection and take advantage of newer technologies.

Some of the recent changes in the meat and poultry inspection systems in the United States have been perceived by consumer advocates, and inspection staff in the field as compromising human health and safety. Their concerns have centered on several issues, including the rate which slaughtered animals move through inspection, the necessity and efficiency of 100% antemortem and postmortem inspection of groups of animals that seem to be nearly uniformly healthy, the actual health hazard presented by microbial contamination of the meat and poultry supply, and the health effects of low-level contamination of meat and poultry by pesticides, drugs, and environmental contaminants. Some observers are further concerned that USDA has not adopted newer technologies to provide information and feedback that could improve the health of livestock and poultry or to address current health hazards, both microbiological and toxic.

Mr. Chairman, food safety inspection systems are currently divided among several government agencies including USDA, HHS, and the Departments of Commerce (National Marine Fisheries Service), and to a lesser extent, the Department of Defense. In order to circumvent bureaucratic obstacles to respond to emergency food safety situations, food safety inspection systems should be consolidated, thus, creating a centralization of authority. Consolidation of food safety inspection systems would also allow the agency with jurisdiction to create a critical mass of food safety experts which would include veterinarians, physicians, pathologists, toxicologists, microbiologists, epidemiologists, food scientists and others. These food safety experts could further implement a uniform approach to handling emergency food safety situations.

In my time in government there were several key food safety issues that were so contentious that they got all the way up to meetings between Cabinet secretaries or Assistant secretaries before being adjudicated. These included: regulation of bovine interferon; salmonella in eggs; nutrition labeling; listeria in food; and fish inspection. I believe that if anyone here today had sat in on any one of those they would have become an advocate for consolidating all of food inspection in one department.

Historically, predecessor food safety (FDA and FSIS) agencies were located in USDA. A consolidated agency should probably be reorganized under the Department of Health and Human Services in order to provide the uniform approach, cost savings, and centralization of authority that I just mentioned.

Had there been in 1906 a Department of Health, I suspect FDA and the Meat Inspection Program would have been placed there. Now that there is a health department, I believe that optimum efficiency and cross utilization of personnel could be obtained there.

Mr. Chairman, thank you again for the opportunity to participate in this hearing. I look forward to working with this committee and interested members of Congress and the administration in achieving progress in reforming meat and poultry inspection.

Mr. TOWNS. Dr. Menning.

STATEMENT OF EDWARD L. MENNING, D.V.M., M.P.H., EXECUTIVE VICE PRESIDENT, NATIONAL ASSOCIATION OF FEDERAL VETERINARIANS

Dr. MENNING. Mr. Chairman, I am very pleased for the NAFV to respond to the committee's request to comment. We are not newly involved in the points that we are about to make since we have testified before Congress in many meetings for 12 solid years, all to no avail.

I would like to start by highlighting a few of the comments that have been made elsewhere, et cetera, that seem to denigrate the antemortem/postmortem organoleptic inspection and also involved in sort of bashing veterinarians.

Individual carcass inspections are a critical point in the elimination of diseased and otherwise unwholesome meat and poultry in the food supply.

In 1990, an enormous number of diseased food animals were removed: over 180,000 cattle/calves, over 190,000 swine, over 20,000 sheep and goats, over 3.5 million turkeys and ducks, and over 81 million chickens. Over 70 percent of all those millions were for infectious diseased reasons.

The requirement and justification for this kind of inspection is unique to food animals. Diseases of animals are not static, and they have been and will be sentinels of new and changing patterns of disease.

This changing of disease potential is exemplified in the past 20 years by the "new" public health risk from campylobacter, listeria, E. coli, and salmonella enteritidis.

The first control program in all HACCP programs is always the safety of the raw food received. This is for meat and poultry, the live animal in antemortem/postmortem organoleptic inspection which is the only available intervention and which is quite rapid. Indeed, this is one area where FSIS excels by assuring that no diseased animals enter the food chain.

Organoleptic evaluation should not be ridiculed. It is still the evaluation that physicians use when first seeing a new patient. And only following indications from their organoleptic evaluation are further tests studied. Veterinarians are considered to be the only public health experts for meat and poultry across-the-board and for food hygiene by everyone in the world in most countries of which they predominate even more than they do in the United States.

Veterinarians have discovered most of these meatborne disease organisms. In fact, salmonella is named after one. Veterinarians have developed most of the tests for these diseases, have defined the methods of transmission for these diseases. And most of the world's literature in this area has veterinary authors.

Better medical-technical scientific graduate training or continuing education for everyone in FSIS is desperately needed if a more scientifically credible program is to follow. Nothing is presently being done. Millions are spent for supervisory managerial training and union meetings across the entire country, but no one can attend a scientific meeting to improve or update their medical-tech-

nical abilities. Persons with no scientific credentials whatsoever are routinely placed in charge of public health studies or programs.

What to do? One, change the law to give authority for preharvest inspection to USDA, APHIS, and require adequate trace-back controls. The present meat and poultry laws appear to adequately allow and cover for microbiological controls should USDA personnel have the political will to institute them.

Two, fund programs adequately to meet your risk-benefit objectives, whatever those may turn out to be. This has been done in the past adequately for what Congress wanted. Put scientifically credentialed people in charge of science and public health programs and keep them up-to-date on scientific facts as well as managerial abilities. This is not being done and has not been.

Four, gather baseline microbiological data for risks of healthy carcasses. This is where all the disease is presently coming from. Healthy carcasses are contaminated by feces directly or indirectly once they have been passed for human food. This has been begun by FSIS.

Gather baseline microbiological data for risks on condemned carcasses, since they often contaminate the hands, equipment, and other carcasses. In the 70 percent of those millions condemned, they have very little idea what is there. This is not being done.

Gather baseline microbiological data on whether sanitizing is really sanitizing. They do not know, yet they require it in many, many points throughout plants. This is not being done.

Immediately evaluate ways to reduce fecal contamination. If you get rapid microbiological tests, what are you going to do? Rapidly identify the bacteria that we knew got there from the feces and then condemn it all?

We must start reducing the fecal contamination to begin with. With the above, a more rational risk assessment can be made to determine what preventive interventions should be involved. We must move toward pasteurization of high risk, raw product, be that heat or irradiation. Pasteurization for hamburger will be the only solution as it was for milk, since you can never have it risk free.

Finally, I was 1 of the 10 members on the NPR food safety task force. We unanimously recommended a single independent food safety agency, not a move to FDA. If an independent agency is not an option, then meat and poultry remaining in USDA is probably the only logical cost-effective option.

It makes no sense to move FSIS, under the guise it would have better results in FDA when, as a matter of fact, all the animal scientific research and expertise is in USDA and all these diseases are from animals and from their feces.

Of the last 15-year period, of all the outbreaks where food was implicated, over 3,600, 23 percent, of the outbreaks and 24 percent of the cases were from foods totally under USDA control. The rest were out of their control.

The final report of the Advisory Committee on the Food and Drug Administration——

Mr. TOWNS. Doctor, could you summarize? Your time is up.

Dr. MENNING. I have just two sentences.

The final report of the advisory committee on the Food and Drug Administration, May 15, 1991, stated, "No evidence was presented

to the subcommittee to show that FDA's performance would improve if its human food responsibilities were combined with those of USDA."

With the above in mind and the other problems cited in that report, we would recommend leaving it where it is but force them, with the knowledge at hand, to improve their microbiological standards.

Thank you.

[The prepared statement of Dr. Menning follows:]

STATEMENT

OF

EDWARD L. MENNING, D.V.M., M.P.H.

NATIONAL ASSOCIATION OF FEDERAL VETERINARIANS

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES

AND INTERGOVERNMENTAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

NOVEMBER 4, 1993

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BIOGRAPHICAL SKETCH

EDWARD L. MENNING, DVM, MPH

Dr. Menning received his Doctor of Veterinary Medicine from The Ohio State University in 1955 and his Masters in Public Health from the University of Michigan.

He has been Executive Vice President, National Association of Federal Veterinarians since 1980. Prior to which he had served 26 years as a veterinary officer in the United States Air Force, of which the last 4 1/2 years he was Assistant Surgeon General for Veterinary Services retiring from the USAF in 1980.

He is board certified as a specialist in public health by the American College of Veterinary Preventive Medicine and is a member of numerous public health and veterinary societies.

His special interests are animal diseases that can be transmitted to humans, food hygiene and food-borne diseases.

REINVENTING THE FOOD SAFETY SYSTEM--U.S. DEPARTMENT OF AGRICULTURE'S (USDA) PROGRESS IN REFORMING MEAT AND POULTRY INSPECTION

Background

The National Association of Federal Veterinarians has a membership of approximately 1500 veterinarians of which over 900 are employed by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) as experts in the general area of public health, and specifically in the field of food hygiene. They provide the professional medical services, supervision and management of FSIS programs for the antemortem and postmortem inspection of all food animals, and the inspection of some meat and meat products prepared therefrom. The men and women who are the FSIS veterinarians are dedicated public servants who are sincerely concerned that any changes in the nation's food hygiene programs be made in the best interest of the health, nutrition and economic welfare of the public.

Well meaning spokespersons and persons with hidden agenda state that U.S. citizens enjoy the safest, most affordable and most abundant meat and poultry supply in the world. That statement may be largely true. However, the same meat and poultry annually results in illnesses of many thousands of Americans and deaths of some. There is, indeed, much that should be done to improve the quality of meat hygiene in this country that can be enormously beneficial to the meat consuming public, as well as to the producers, processors and purveyors of meat animals and meat products.

Quality meat inspection is costly, but the human disease and economic fraud that it can prevent when responsibly administered can make it a bargain. For example, the total cost of inspecting all meat and poultry produced in the U.S., imported and exported, including all overhead and extraneous costs is less than two dollars per U.S. citizen per year. While the current program prevents much human disease, estimates of the costs of preventable diseases which are still acquired from meat each year exceed the annual FSIS budget.

Meat is the most costly portion of our diet. As such, it presents a constant temptation to the few unscrupulous, or merely pragmatic, industry members who would profit from the marketing of diseased animals, the adulteration or concealment of inferiority of meat products, or from policy changes that promote industrial productivity at the expense of effective inspection methods.

The Federal Meat Inspection Act of 1907 and the Poultry Products Inspection Act of 1957 (both Acts were updated in the late 1960's) mandate that the Department of Agriculture provide continuous inspections at slaughter plants examining each carcass. Such inspections are a critical point in the elimination of diseased and otherwise unwholesome meat and poultry from the food supply. For example, in 1990 these

inspectors eliminated an enormous number of diseased food animals from our nation's meat supply--over 180,000 cattle/calves, over 190,000 swine, over 20,000 sheep/goats, over 3 1/2 million turkeys/ducks and over 81 million chickens. This is of particular importance to the task of protecting consumers from foodborne disease because most of the disease agents that are particularly hazardous to humans may be carried by and transmitted through the meat of diseased food animals. The requirement, and justification for this kind of inspection is unique to food animals. A good analogy of diseased animal risk is the egg. Until a few years ago grade A uncracked eggs were known to be safe to eat raw. The only danger was from surface contamination on the shell (similar to surface contamination on a healthy beef carcass). Then, for unknown reasons, Salmonella enteritidis gained the ability to cross the ovary and become situated within eggs (similar to a diseased beef carcass). Thus far these eggs in the past 5 years have caused over 7,000 cases of disease and over 50 deaths in the U.S. Eggs, by the way, are not under FSIS control.

Diseases of animals are not static, they have been and will be sentinels of new and/or changing patterns of disease. Furthermore, assessing disease patterns for one geographic area (as has been proposed) is reasonable only when animals are not shipped all over the U.S. for slaughter such as exists now. This changing of disease potential is exemplified in the past 20 years by the "new" public health risk from Campylobacter, Listeria, Yersinia, Escherichia coli 0157:H7 and Salmonella enteritidis.

The first Critical Control Point in all Hazard Analysis Critical Control Point (HACCP) programs is always the safety of the raw food received. This is the live animal for meats and antemortem/postmortem organoleptic (sight and touch) inspection is the only available intervention. Indeed, this is one area where FSIS excels by assuring that no diseased animals enter the food chain. The purpose of the examination is to determine the suitability of the carcass for use as human food. The innumerable specific diseases that may affect food animals produce lesions, many of which, are identical to those produced by other diseases. A specific diagnosis is seldom possible, but an appropriate, rational disposition, based on the veterinarian's knowledge of the affect of disease processes on the animals is usually possible. Many, but not all, of the diseases which affect food animals are caused by infectious, toxic or physical agents that are hazards to human health. Traumatic injury and physiological abnormalities may, also, result in disease conditions that render an animal unfit for food.

All systemically diseased carcasses are unfit for human food. If the disease condition is limited to a part of the carcass, that part must be condemned. For this reason, a definitive diagnosis is not necessary to identify carcasses that

may bear hazards to human health.

Traditional inspection systems are very effective in removing organoleptically detected abnormalities, but cannot be assessed for risk benefit because data is not available for determining the etiology of the abscesses, septicemia, toxemia, etc. That causes the condemnations. The lack of data on these diseases is one of FSIS' risk assessment failures.

Organoleptic evaluation should not be ridiculed as has become a fad by the ignorant. Organoleptic evaluation is what every physician does when first evaluating a patient and only when the organoleptic findings indicate the need are further tests made.

Before we go further, let's look at how "public health persons" would/could correct all the damage that having primarily veterinarians in these programs have allowed as stated frequently this year. There is no such thing as a "silver bullet" public health expert. . There are chronic disease experts, sexually transmitted disease experts, epidemiologists, sanitarians, veterinarians, etc. who make up the "public health umbrella." Veterinarians are considered to be the only public health experts for meat/poultry (and other areas) by every country in the world in most of which they predominate even more than in the U.S. Veterinarians have discovered most of these meatborne disease organisms (Salmonella is named after Dr. D. E. Salmon). Veterinarians have developed most of the tests for these diseases, veterinarians have defined the methods of transmission for most and most of the world's scientific literature in this area has veterinary authors. There is no other public health person who can protect the health of people rather than protect the health of pigs and to state otherwise is naive at best. The medical knowledge and abilities are present but "political" constraints have not allowed veterinarians to do what is necessary to reduce the risks in most instances following the postmortem disposition (all of which will be discussed later).

The present meat/poultry inspection laws adequately provide the legal basis for implementing better microbiological controls if the political will exists to do so with the possible exception for a broader pre-harvest inspection program.

What went wrong?

(NAFV has for 12 years testified to all the following before Congress numerous times and had discussions with staff numerous times; presented papers and discussions with the Secretaries of USDA, Assistant Secretaries and Administrators numerous times; participated in many symposia; was interviewed by many media and published numerous papers. All to no avail. Now E. coli 0157:H7 is driving a speeding train down an unknown track.)

First and foremost. The Agency has evolved into a mindset that the only skills/knowledge required of their supervisors and managers are supervisory/managerial/negotiating skills. Medical/technical knowledge is not needed. This has been stated numerous times by top management. Other philosophies that have evolved are: "it's better to be uniform than preventively correct" and "contamination of carcasses from external sources such as condensate, grease, etc. are to be prohibited but contamination from internal sources, i.e. feces, is normal and OK if not visible."

The need for current medical/technical knowledge is not recognized as pertinent to the mission since the mission has evolved into solely a "tallying of visual events." Without current knowledge and appreciation of public health impact in all levels of field operational control, there cannot be a science-based food safety program. If managers do not understand they cannot lead, motivate, evaluate, solve problems, assess changes, etc. based on current knowledge in areas of microbiology, sanitizing, food science, epidemiology, risk assessment, pathology and public health.

Inspectors with high school degrees are trained at government expense not to gain more technical knowledge that can be applied to the mission, but purely to make them eligible for promotions to higher level management positions. No degree is required. The course hours can be and are satisfied by correspondence courses. These "false" food technologists now can apply for any area or regional positions that had been medically credentialed. When they apply, they are on a separate list from the veterinarians who apply, so that the food technologists do not even compete with veterinarians. There are two job descriptions for each of these jobs and the one used is dependent on who is selected, i.e., a doctor or a "nothing." NAFV strongly supported a food technology training program requiring graduate training in meat/poultry food technology and still does.

Continuing medical/technical education has been totally absent after initial training by FSIS. (The new small refresher course at TAMU and the Ames Correlation Group are a step to help in this.) Up to now, no updating of scientific knowledge has been given, encouraged nor often even allowed. Even in-house studies to inform your peers are discouraged or not allowed. Area/regional/national meetings when held by FSIS, contain neither scientific discussion nor new science information of <u>any kind</u>!

No one, for many years, has been sent for advanced training in any science area (microbiology, toxicology, epidemiology, meat/poultry science, etc.) except pathology and a very general indoctrination-type program in science.

Scientific knowledge and its application to mission objectives is ignored as a prerequisite for promotion within the entire inspection operations. Persons selected to chair and be members of scientific committees and taskforces frequently have no scientific credentials.

None of the pilot tests for new inspection programs (SIS or before) have ever attempted to evaluate their effect on disease and/or spoilage organisms.

There have been no baseline data collected on bacterial public health risk, if any, from condemned carcasses. There have been no baseline data collected on bacterial public health risks on the "passed" carcasses. Without baselines, trends and interventions cannot be evaluated.

Sanitizing has not been evaluated. Hot water and/or chemical sanitizers have as their only purpose the killing of bacteria (disease and/or spoilage). FSIS has not tested the many significant variables under which they're used which can prevent their effectiveness nor are they even required in poultry slaughter facilities.

Numerous ways of washing or trimming feces from carcasses have been evaluated for visible effectiveness only, but little, if anything has been done to try to prevent the fecal contamination from happening in the first place.

What is FSIS doing now?

1. FSIS has slowly begun to gather baseline microbiological data on beef, downer cattle and hamburger, none of which will be statistically valid for a plant (according to FSIS). Therefore, if a new inspection program is to be tested they may not be able to compare its impact on raising or lowering risk in that plant.

2. FSIS has developed a pathogen reduction program which contains many questions seeking scientific answers and contains recommendations for development of rapid microbiological tests and preharvest evaluations of animals and agents of risk on the farms. These are needed. These are all expensive and long-term. There is little (unless it's hidden) in the pathogen reduction program that would expand the use of 30-40 year old scientific methods such as:

a. Evaluating the cleanliness of hands, steel mesh gloves, cloth gloves, knives used to trim feces and abscesses, etc.

b. Determining the agents responsible for the infectious disease that causes the condemnation of about 70% of the millions of carcasses mentioned earlier.

c. Deciding what to do with the rapid tests if and when available since almost all (if not all) the organisms of risk get on the healthy carcasses directly or indirectly from feces which we already know. We know how they get there we just don't know

the variety present. Will they allow the contamination to continue and then detect it rapidly or would it make more sense to reduce the contamination to begin with using washing of live animals, better evisceration procedures, slower lines, etc.?

d. With preharvest inspection much valuable information can be gained, but what are realistic expectations? Thousands of more federally employed people running around testing billions of animals? If, as many suspect, 10% of cattle have E. coli 0157:H7 are you going to condemn these approximate 10 million head and pay billions in indemnities? Or more realistically would one have a voluntary certification program that could be effective for some farms? The "great expectations" for a preharvest quick fix by many groups is comically pathetic.

e. Better education of the consumer is needed, but the expectations here are also unrealistic. About 25% of the U.S. population is immunocompromised and is growing quantitatively and qualitatively. Handling raw product in the home and restaurant can be dangerous even if subsequently cooked well. Most such education programs have been amazingly unsuccessful. Much of our food is now prepared by others over whom we have no control. The turnover rate in fast food restaurants is 200% per year or higher. These employees are not even in place long enough to be trained well and many cannot read. Thus, we must reduce the risk for raw products of highest risk.

f. Better medical/technical/scientific graduate training and or continuing education is desperately needed if more scientifically credible programs are to follow. Nothing is being done. Millions are spent for supervisory/managerial and union meetings everywhere. But no one can go to school or attend a scientific meeting for their own knowledge. Still at the presently scheduled FSIS meetings no science is discussed only administration!

What to do?

1. Change the law to give authority for preharvest inspection to USDA/APHIS and require adequate traceback controls.

2. Fund programs to meet your risk/benefit objectives, whatever they may be.

3. Put scientifically credentialed people in charge of all science or public health programs and keep them up-to-date and promote on scientific abilities as well as managerial abilities.

4. Gather baseline microbiological data for risks on healthy carcasses.

5. Gather baseline microbiological data for risks on condemned carcasses (since they often contaminate hands, equipment and healthy carcasses).

6. Gather baseline microbiological data on whether sanitizing

is really sanitizing.

7. Immediately evaluate ways to reduce fecal contamination.

8. Improve consumer education.

9. With the above a more rational risk assessment can be made and preventive interventions can then be put in place.

10. Try to move to pasteurization of high risk raw product with the use of heat, irradiation, etc. Pasteurization for hamburger will be the only solution as it was for milk. Without pasteurization raw meat will never be risk free.

What about the National Performance Review recommendation?

I was one of 10 members on the NPR food safety task force. We unanimously recommended a single independent food safety agency, not a move to FDA.

If an independent agency is not an option, then meat and poultry remaining in USDA is the only logical cost-effect option. It makes no sense to move FSIS under the guise it would have better results in FDA when:

a. All the animal scientific expertise is in USDA, APHIS and ARS.

b. Of the latest fifteen year period studied (1973-1987) of the 3,699 outbreaks where the disease had an implicated food only 23% were from generic products under FSIS control. Of the major foodborne disease outbreaks known in the last 10 years only one, the Washington E. coli, implicated FSIS controlled food, the others were all dairy, eggs and seafood involving over 30,000 cases of diseases and over 70 deaths. Why should FSIS be moved to improve it rates of about 600 cases and 5 deaths?

The final report of the Advisory Committee on the Food and Drug Administration, May 15, 1991 showed inadequate facilities, training and funding for foods. This report was highly concerned about the viability of the foods program and the lack of Agency priority for food issues. The report also stated and I quote

> "No evidence was presented to the subcommittee to show that FDA's performance would improve if its human food responsibilities were combined with those of USDA, if it were given EPA's responsibilities or setting pesticide tolerances, or if it were empowered to regulate advertising for foods and cosmetics."

Finally, I reviewed a draft of the FDA Unicode for Food Sanitation in 1982, it still isn't published.

FDA has no baseline data on risks.

The E. coli fast food chain in Washington state was in compliance with the FDA Sanitary Code though not in compliance with the state code.

With the above in mind it makes no sense to move FSIS into FDA, in fact it appears to be contraindicated.

Mr. TOWNS. Mr. Carney.

STATEMENT OF DAVID CARNEY, LEGISLATIVE COORDINATOR, NATIONAL JOINT COUNSEL OF FOOD INSPECTION LOCALS

Mr. CARNEY. The National Joint Council of Food Inspection Locals would like to thank this committee for the opportunity to present the views and positions outlined in the four agenda topics.

I am David Carney, employed as a food inspector for the Food Safety and Inspection Service. And I am one of those nasty labor officials that the previous panel member just referenced.

I represent and am president of the North Central Council. As a member of the executive body of the National Joint Council, I maintain the position of legislative coordinator.

As a food inspector, I have inspected in the slaughtering of all red meat species and the processing of meat and poultry. I am presently assigned as a relief inspector to a large bacon and ham processing establishment. For time-in-service, I have been a food inspector for 16 years and labor representative for 14 years and in the position I now maintain for 7 years.

I will address the four topics as briefly as possible.

As a food inspector and a labor representative, the National Joint Council has experienced several progressive reforms. But these reforms are to counter the results from 12 years of attempted deregulations meant to accommodate the industry that we regulate.

Unfortunately, the reforms that will be illustrated were not often easy to achieve: One, SIS-cattle abolishment, not a given, but an all out battle. We had to fight to get that removed from FSIS initiatives.

Two, the scrapping of a volatile HACCP program.

Three, an attempt to eradicate contaminants on red meat.

Four, a prolonged pathogen reduction program.

Five, a more comprehensive preoperational sanitation program for slaughter operations.

And, six, an attempt to identify a microbiological sampling program for equipment on slaughter production.

The most important reform that the National Joint Council has experienced is to observe FSIS management move from a covert form of inspection development programs to overt.

Historically, the inspection force was never subjected to forms of preventing, control, reduction or the elimination of contaminants to eradicate microorganisms that contribute to foodborne pathogens. We have been taught to deal with contaminants through the regulated organoleptic inspection programs.

The mentalities of previous FSIS administrators and administration, was not to address this initiative but to permit the washing of feces in poultry, faster line speeds to accommodate the industry and no punitive damages. And as I have criticized previous FSIS management, this lack of concern for removing contaminants lead me to believe that FSIS was trying to figure out how to make feces palatable.

However, in the last 1½ years, FSIS has made an attempt—I emphasize "attempt"—to prevent, control reduce, or eliminate risks of foodborne illness. By attempt, I refer to acidic spraying,

trisodiumphosphate dips, identification of critical control points, risk assessment of processes, microswabbing and quick test kits for identification of foodborne pathogens.

Let me reiterate, these are programs that are not here.

All of these have been subjected to severe criticism, even though these are far from being scientifically sound, this is a lot more than we have ever had.

It is the recommendation of the National Joint Council that to develop an optimal regulatory food safety system would be to maintain the Food Safety and Inspection Service in its present form; however, it should become an autonomous agency to continue meat and poultry inspection based on scientific principles free of outside influence from "pork barrel" bureaucrats and profit motivated industry. We would further recommend that FSIS be removed from the authority of USDA Marketing and Inspection, with direct reporting to the Secretary of Agriculture from a self-governing body, compromised of management, supervision, and the labor-inspection force.

Development of inspection principles and regulatory programs would be done through consensus building from the FSIS self-governing body, consumer constituents, industry, and scientific academia.

To comment on Vice President Gore's recommendation on the elimination of FSIS can simply be stated as—irresponsible, misinformed, and ludicrous. It is the position of the National Joint Council that to move FSIS to FDA would be regression not progression. FDA is a reactionary agency based on the self-inspecting industries that it attempts to regulate. FDA is not in every plant every day nor does FDA maintain the daily inspection records as compared to FSIS. Our inspectors account for inspection functions for sanitation, disposition of carcasses, formulation of products, accuracy of label approvals and allied functions.

I would like to give two examples I have personally dealt with FDA in plants I regulate.

One is a pizza operation with a very serious problem with gross contamination from insecticide fumigation. There was product contaminated by this fumigation. FDA had responsibility in that plant. FDA did not take control of it. I had to condemn the product. And when FDA was notified, the FDA person simply called me and asked me if I would take action on his part.

The second action, I was assigned to a turkey processing plant. I discovered sodium tripolyphosphate contaminated with metal particles. I rejected all of the product at the time. FDA was notified. Once again, I was asked to perform sampling functions for the FDA person. When I refused, 2 days later someone arrived to collect a sample.

Now my question to this committee is: Is this the type of FDA inspection that you want for meat and poultry products that can be slaughtered, processed, shipped, and consumed within 24 hours?

In the past, the National Joint Council has been very critical of the Food Safety and Inspection due to impromptu regulatory programs, but FSIS is not beyond salvage. FSIS is not an Edsel that needs to be scrapped, but a Thunderbird that is continuously redesigned to meet customers' demands.

To further comment on Vice President Gore's concern for food safety and his rendition of how chickens are inspected on the Phil Donahue show as pathetic. His actions were certainly wrong and demoralizing to our inspectors. If Vice President Gore wanted to portray the truth, he should have depicted how industry has influenced previous USDA officials to permit washing of feces, faster line speed less condemnations, and harassment of our inspectors by a greedy industry.

To conclude, what I have just expressed is something that we want to prevent, in any future changes. The National Joint Council would recommend that if our proposals are adopted, we commit to work and develop the finest inspection program that the consumers deserve.

Mr. TOWNS. Thank you very much.

[The prepared statement of Mr. Carney follows:]

National Joint Council of Food Inspection Locals
OF THE AMERICAN FEDERATION OF GOVERNMENT EMPLOYEES
AFFILIATED WITH THE AFL-CIO

MID ATLANTIC MIDWEST | NORTH CENTRAL NORTHEAST | NORTHERN SOUTHERN | SOUTHWEST WESTERN

TESTIMONY OF
DAVID CARNEY
LEGISLATIVE COORDINATOR
NATIONAL JOINT COUNCIL OF
FOOD INSPECTION LOCALS, AFGE

"Reinventing the Federal Food Safety System--U.S. Department of Agriculture's (USDA) Progress in Reforming Meat and Poultry Inspection."

The National Joint council would like to thank this subcommittee for the opportunity to represent the views and positions outlined in the four agenda topics.

My name is David Carney, employed as a Food Inspector for the Food Safety and Inspection Service and President of the North Central Council of Food Inspection Locals. As a member of the executive body of the National Joint Council, I maintain the position of Legislative Coordinator.

As a Food Inspector, I have inspected in the slaughtering of all red meat species and the processing of meat and poultry. I am presently assigned as a relief inspector to a large bacon and ham processing establishment. For time-in-service, I have been a Food Inspector for sixteen years and labor representative for fourteen years and in the position I now maintain for seven years.

(1) The progress USDA is making to reform its' meat and poultry inspection programs:

As a Food Inspector and labor representative, the National Joint Council has experienced several progressive reforms. But these reforms are to counter the results form twelve years of attempted deregulations meant to accommodate the industry that we regulate.

Unfortunately, the reforms that will be illustrated were not often easy to achieve. 1. SIS-cattle abolishment (not a "given", but an all out battle) 2. the scrapping of a volatile HACCP program 3. an attempt to eradicate contaminants on red meat 4. a prolonged pathogen reduction program 5. a more comprehensive pre-operational sanitation program for slaughter operations and 6. another attempt to identify a microbiological sampling program for equipment on slaughter production.

The most important reform that the National Joint Council has experienced is to observe FSIS management move from a covert form of inspection development programs to overt.

(2) The extent to which the existing Federal Food Safety System, specifically, meat and poultry inspection, is designed to prevent, control, reduce or eliminate the primary risks of food borne illness;

Historically, the inspection force was never subjected to forms of preventing, control, reduction or the elimination of contaminants to eradicate microorganisms that contribute to food borne pathogens. We have been taught to deal with contaminants through the regulated organoleptic inspection programs.

The mentalities of previous FSIS administrators and administration, was not to address this imitative, but to permit the washing of feces in poultry, faster line speeds to accommodate the industry and no punitive damages. And as I have criticized previous FSIS management, this lack of concern for removing contaminants lead me to believe that FSIS was trying to figure out how to make S _ _ _ (feces) palatable.

However, in the last year and a half, FSIS has made an attempt to prevent, control reduce or eliminate risks of food borne illness. By attempt, I refer to acidic spraying, trisodiumphosphate dips, identification of critical control points, risk assessment of processies, micro swabbing and quick test kits for identification of food borne pathogens.

All of these have been subjected to severe criticism. even though these are far from being scientifically sound, this is a lot more than we have ever had.

(3) The major components and guiding principles of an optimal federal food safety system and options for developing and implementing such a system:

It is the recommendation of the National Joint Council that to develop an optimal regulatory food safety system would be to maintain the Food Safety and Inspection Service in its' present form, however, it should become an autonomous agency to continue meat and poultry inspection based on scientific principles free of outside influence from "pork barrel" bureaucrats and profit motivated industry. We would further recommend that FSIS be removed from the authority of USDA Marketing and Inspection, with direct reporting to the Secretary of Agriculture from a self governing body, compromised of management, supervision and the labor/inspection force.

Development of inspection principles and regulatory programs would be done through consensus building from the FSIS self governing body, consumer constituents, industry and scientific academia.

(4) Your views and opinions of the September 7, 1993, recommendations of the Vice President's National Performance Review

to "Eliminate the Food Safety and Inspection Service as a separate agency by consolidating all food safety responsibilities under the Food and Drug Administration."

To comment on Vice President Gore's recommendation on the elimination of FSIS can simply be stated as --- irresponsible, misinformed and ludicrous. It is the position of the National Joint Council that to move FSIS to FDA would be **REGRESSION** not **PROGRESSION**! FDA is a reactionary agency based on the self inspecting industries that it (FDA) attempts to regulate. FDA is not in every plant every day nor does FDA maintain the daily inspection records as compared to FSIS. Our Inspectors account for inspection functions for sanitation, disposition of carcasses, formulation of products, accuracy of label approvals and allied functions.

EXAMPLE:
My personal involvement with FDA in two plants that I have inspected at;

1. A pizza plant with pizza assembly and production, which is under daily inspection form FSIS had the bakery portion of the plant under FDA authority. I was assigned to this plant (meat ingredients) for over three years and never once saw the FDA inspector. At this plant, an incident of gross contamination from insecticide fumigation resulted in thousands of pounds of product to be condemned. I was required to take action, based on FSIS regulations and the FDA inspector did not even show up to assume his responsibilities. This arrogant FDA person simply called me and asked if I would take action on his part.

2. At a turkey processing plant, on a routine FSIS inspection task, I discovered sodium tripolyphosphate (STP) contaminated with metal particles. All of the STP was placed under USDA **REJECTION** and FDA notified. Once again, I was asked to perform sampling functions for the FDA person. When I refused, two days later, someone arrived to collect a sample.

Now my question to this subcommittee, is this the type of FDA inspection that you want for meat and poultry products that can be slaughtered, processed, shipped and consumed within 24 hours?

In the past, the National Joint Council has been very critical of the Food Safety and Inspection Service due to ispromptu regulatory programs, but FSIS is not beyond salvage. FSIS is not an Edsel that needs to be scrapped, but a Thunderbird that is continuously redesigned to meet customers demands.

To further comment on Vice President Gore's concern for food safety and his rendition of how chickens are inspected on the Phil Donahue show was pathetic. His actions were certainly wrong and demoralizing to our Inspectors. If Vice President Gore wanted to portray the truth, he should have depicted how industry has influenced previous USDA officials to permit washing of feces, faster line speed, less condemnations and harassment of our Inspectors by a greedy industry.

To conclude, what I have just expressed is something that we want to prevent, in any future changes. The National Joint Council would recommend that if our proposals are adopted, we commit to work and develop the finest inspection program that the consumers deserve.

Mr. TOWNS. Mr. Wilson.

STATEMENT OF GARY WILSON, DIRECTOR, ANIMAL HEALTH/ INSPECTION, FOOD POLICY AND RESEARCH, NATIONAL CATTLEMEN'S ASSOCIATION

Mr. WILSON. Thank you, Mr. Chairman. The National Cattlemen's Association would like to thank the committee for the invitation to participate in today's hearing.

NCA represents over 230,000 cattle producers across this country. We hope our response to the subcommittee's questions will be helpful.

In regard to USDA program progress on meat inspection reform, NCA supports efforts to improve the meat and poultry inspection system through the proposed track I and track II initiatives. Program change based on science is the only way to improve the effectiveness of the system, eliminate political bias, and promote common good.

Risk analysis, research on why and how microbiological contaminants grow, development of management systems for control are logical and necessary steps.

Since 1988, NCA has asked the Department to improve the meat inspection system by implementing new methodologies and technology that will assist both plant employees and meat inspectors to do a better job.

Although NCA, too, is easily frustrated with the slow movement of government, we recognize that it is not always the Department's fault. Activists have opposed virtually every new technology designed to improve the meat inspection system. For instance, the National Academy of Sciences endorses the streamline inspection system as being superior to current methods. Yet the hidden agenda of activists killed SIS. Activists have so poisoned the consumer climate for irradiation that poultry and pork industries have yet to implement or use this proven safe technology.

Organic acid wash is being criticized even though scientific data proves it reduces pathogens on carcasses.

USDA's initiatives to establish a proposed rule mandating implementation of HACCP systems for meat and poultry packing plants has been delayed twice by requests of the Safe Food Coalition.

[NOTE.—Mr. Wilson subsequently informed the subcommittee that this was a misstatement of fact. See his December 23, 1993, letter to the subcommittee in appendix 1.]

Mr. WILSON. In the absence of constructive criticism, those with agendas other than promoting public health through scientifically based inspection systems must also be construed as being a major part of the problem.

To outline the extent to which the existing meat inspection system can address foodborne illness, the current inspection system was designed primarily to eliminate diseased livestock and poultry from the food supply.

To that end, it has been very effective in protecting consumers from diseases such as brucellosis, tuberculosis, avian influenza, trichinosis, and others. But this system, based on sight, smell, and feel, is limited in its ability to deal with microbiological hazards.

NCA supports enhancing the meat and poultry inspection system by incorporating scientific analysis for microbiological contaminants.

To outline the major components and guiding principles of an optimal food safety system, NCA believes it is in the consumer's and producer's best interest for the meat and poultry inspection system to be effective and beyond reproach. Public confidence in the safety of beef is of paramount importance to our members.

To accomplish this, the major components of the future meat and poultry inspection system should be risk assessments and scientific analysis supported by hazard analysis and critical control point systems, or HACCP systems.

The guiding principles of an optimal food safety system—you asked us to outline what we feel it would be.

An assessment of hazards associated with each operational step of producing, processing, distributing, marketing, preparing, and consuming food that may result in foodborne illness; a determination of the best place or places in the food chain to control identified hazards; the establishment of safety criteria which must be met at each identified control point; the establishment of procedures to monitor the critical control points; the establishment of corrective action to be taken when there is a problem; the establishment of effective recordkeeping systems that document the formal procedures followed in producing and evaluating the product's safety; and the establishment of test and procedures to verify the food safety system is actually working.

The options for developing and implementing this system will vary from farm to farm, plant to plant, restaurant to restaurant, retail store to retail store, and home to home.

However, to get the process started, a national HACCP guideline should be established as soon as possible. The Department's HACCP roundtable approach appears to be designed to bring all interested parties together to establish the proposed rule. Unfortunately, the Department continues to go along with the Safe Food Coalition's delaying tactics.

[NOTE.—Mr. Wilson subsequently informed the subcommittee that this was a misstatement of fact. See his December 23, 1993, letter to the subcommittee in appendix 1.]

Mr. WILSON. To present our views on the Vice President's proposal to move meat inspection to FDA: NCA policy supports the establishment of a food/safety agency under the jurisdiction of USDA.

Our policy is based on the fact that USDA already has an infrastructure that provides research, guidance, and technical support to producers on a daily basis, none of which exists between producers and FDA today.

The Food Safety and Inspection Service, the Agricultural Research Service, the Animal and Plant Health Inspection Service, the Cooperative State Research Service, and the Extension Service all play a vital roll in working with producers in detecting and controlling animal diseases and improving product quality and safety.

As the system moves toward monitoring and control of microbiological contaminants, producer education will more readily take place under an existing structure than one that we have to take time out to develop under FDA.

NCA also believes the time, energy, and resources required to debate and move one agency from one department to another can be better spent researching and developing new diagnostics and technologies that will enable producers, packing plant owners, their employees, and inspectors to do a better job of detecting and controlling microbiological contaminants.

Thank you very much Mr. Chairman.

[The prepared statement of Mr. Wilson follows:]

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Testimony

on behalf of the

NATIONAL CATTLEMEN'S ASSOCIATION

in regard to

Reinventing the Federal Food Safety System
USDA Progress in Reforming Meat and Poultry Inspection

submitted to

Subcommittee Human Resources and Intergovernmental Relations

submitted by

Gary Wilson
Director, Animal Health/Inspection, Food Policy and Research
National Cattlemen's Association

November 4, 1993

The National Cattlemen's Association is the national spokesman for all segments of the beef cattle industry -- including cattle breeders, producers, and feeders. The NCA represents approximately 230,000 cattlemen. Membership includes individual members as well as 46 affiliated state cattle associations and 29 national breed associations.

Good afternoon, my name is Gary Wilson. I am Director of Animal Health and Inspection, Food Policy and Research for the National Cattlemen's Association. The NCA organization serves over 230,000 cattlemen across the United States.

NCA would like to thank the Subcommittee for Human Resources and Intergovernmental Relations for the invitation to participate in today's hearing. We hope NCA's response to the Subcommittees following questions will be helpful as you begin your debate and deliberations.

1. **Outline the progress USDA is making to reform its meat and poultry inspection programs:**

NCA supports efforts to improve the meat and poultry inspection system through the proposed Track I and Track II initiatives. Program change based on science is the only way to improve the effectiveness of the system, eliminate political bias and promote common good.

Risk analysis, research on why and how microbiological contaminants grow, and development of management systems for control are logical and necessary steps.

Since 1988, NCA has asked the Department to improve the meat inspection system by implementing new methodologies and technology that will assist both plant employees and inspectors to do a better job. Although NCA is easily frustrated by slow moving government, we recognize that it is not always the Department's fault. Activists have opposed virtually every new technology designed to improve the meat inspection system. For instance, the National Academy of Sciences endorsed the Streamline Inspection System (SIS) as being superior to current methods, yet the hidden agenda of activists killed SIS. Activists have so poisoned the consumer climate for irradiation that the poultry and pork industries have yet to implement use of this proven safe technology. Organic acid wash is being criticized even though scientific data proves it reduces pathogens on carcasses. USDA's initiatives to established a proposed rule, mandating implementation of HACCP (Hazard Analysis and Critical Control Points) systems for meat and poultry packing plants (like most food processing plants under FDA jurisdiction),has been delayed twice by request of the Safe Food Coalition. In the absence of constructive criticism, those with agendas other than promoting public health through a scientifically-based inspection system must also be construed as being a major part of the problem.

2. **Outline the extent to which the existing federal food safety system, specifically meat and poultry inspection, is designed to prevent, control, reduce or eliminate the primary risks of foodborne illness:**

The current inspection system was designed primarily to eliminate diseased livestock and poultry from entering our food supply. To that end, it has been most effective in protecting consumers from diseases such as brucellosis, tuberculosis, trichinosis and avian influenza only to name a few. But this system, based on sight, smell and feel, is limited in its ability to deal with microbial hazards. NCA supports enhancing the meat and poultry inspection system by incorporating scientific analysis for microbiological contaminants.

3. **Outline the major components and guiding principles of an optimal federal food safety system and options for developing and implementing such a system:**

NCA believes it is in the consumer's and producer's best interest for the meat and poultry inspection system to be effective and beyond reproach. Public confidence in the safety of beef is of paramount importance. To accomplish this, the major components of the future meat and poultry inspection program should be risk assessments and scientific analysis supported by Hazard Analysis and Critical Control Points (HACCP) systems.

The guiding principals of an optimal food safety system are:

- An assessment of hazards associated with each operational step of producing, processing, distributing, marketing, preparing, and consuming food that may result in foodborne illness.
- A determination of the best place (s), in the food production chain, to control identified hazards.
- The establishment of safety criteria which must be met at each identified critical control point.
- The establishment of procedures to monitor the critical control point.
- The establishment of corrective action to be taken when there is a problem identified by monitoring of a critical control point.
- The establishment of effective record-keeping systems that document the formal procedures followed in producing and evaluating the product's safety.
- The establishment of test and procedures for verification that the food safety system is working correctly.

The options for developing and implementing this system will vary from farm to farm, plant to plant, restaurant to restaurant, retail store to retail store and home to home, depending on the resources and problems associated with each segment of the food chain. However, to get the process started, a national HACCP guideline should be established as soon as possible. The Department's HACCP Roundtable approach appeared to be designed to bring all interested parties together to establish the Proposed Rule. Unfortunately the Department continues to go along with the Safe Food Coalition's delaying tactics.

4. **Present your views and opinions of the September 7, 1993, recommendation of theVice President's National Performance Review to "Eliminate the Food Safety and Inspection Service as a separate agency by consolidating all food safety responsibilities under the Food and Drug Administration."**

NCA policy supports the establishment of a food safety/inspection agency under the jurisdiction of USDA.

Our policy is based on the fact that USDA already has an infrastructure that provides research, guidance and technical support to producers on a daily basis, none of which exist between producers and FDA today. The Food Safety and Inspection Service, Animal and Plant Health Inspection Service, Agricultural Research Service, Cooperative State Research Service and the Extension Service at USDA all play a vital role in working with producers in detecting and controlling animal diseases and improving product quality and safety. As the system moves toward monitoring and control of microbiological contaminants, producer education will more readily take place through an existing infrastructure, than one we would have to organize under FDA.

NCA also believes the time, energy and resources required to debate and move one agency from one Department to another can be better spent researching and developing new diagnostics and technologies that will enable producers, packing plant owners and employees and inspectors to do a better job of detecting and controlling microbiological contaminants.

Again, NCA would like to thank the Subcommittee for the opportunity to present the views of the National Cattlemen's Association. This concludes our remarks.

Mr. TOWNS. Thank you. I thank all of you for your testimony.

At this time, I would like to yield to the ranking member, Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

Mr. Chairman, I have to say with regret I have to excuse myself to get ready for a markup that is occurring this afternoon. In English, that means a vote on bills. I wanted to hear all the testimony from this panel. Even though it was conflicting in some respects, it was all very valuable, and I appreciate their expert teams.

I yield back.

Mr. TOWNS. Thank you. You are right. There are a lot of conflicts around here. You have to be in two or three places at once. The markup is very important.

Thank you very much.

We have also been joined by Congressman Portman from Ohio.

Before I yield to him, let me raise a couple of issues.

Ms. Foreman, in 1977, were you with the USDA?

Ms. FOREMAN. Yes.

Mr. TOWNS. In what capacity?

Ms. FOREMAN. Assistant Secretary for Food and Consumer Services, which at that time, Mr. Chairman, had responsibility for meat and poultry inspection and the grading of food. Those were deemed to be consumer services rather than marketing services at that time.

Mr. TOWNS. Right. The Booz-Allen study on meat and poultry inspection, do you remember that?

Ms. FOREMAN. Yes.

Mr. TOWNS. That study recommended—I think in 1977—that USDA begin microbial monitoring.

What happened?

Ms. FOREMAN. The study was actually conducted in 1975 and given to us in 1977. There was opposition to its implementation, and it didn't seem to approach USDA's structure as it then existed.

My own view is that we probably should have implemented major sections of it at that time.

Mr. TOWNS. I am not trying to be confrontational in any kind of way, but I just think we need to sort of get a history here so we know what we are doing.

Exactly why didn't you implement it? Exactly why?

Ms. FOREMAN. Well, I have to recall that the Booz-Allen-Hamilton report was a mechanistic sort of thing.

You are taking me back 20 years now.

Mr. TOWNS. Right.

Ms. FOREMAN. That had microbial testing as a very, very minor part of its recommendations and, as I recall, proposed a continuation of a detailed and staff-heavy structure that didn't seem to be particularly useful.

Instead, in 1978, the Department proposed an alternative to that, which is usually not referenced by people; but we proposed in May 1978 a program that would move toward quality control, move toward some microbial testing, moved toward substantially expanded testing for pesticides in meat and poultry which were a large problem at that time.

Mr. TOWNS. Thank you.

Dr. Walker, is the present meat and poultry system adequate to prevent foodborne disease?

Dr. WALKER. No, Mr. Chairman. I think it is very clear it is not. You have heard any number of witnesses before us affirm that it is not adequate to protect public health. You also heard from us, along with others, that there are a number of corrective actions that should be taken.

We would reemphasize again that we believe it productive and highly desirable to move this program into FDA where we have a corps of health scientists, where we have an agency whose primary function is prevention of disease and dysfunction.

At a time, we are talking about reducing the cost of health care, all the debate about health care reform, it appears to us to be very sound, to emphasize prevention, at every level of the system. That includes the prevention of foodborne diseases that we see as substantially increasing.

I think the logic of the Vice President's recommendation is prevention. It permeates most of the recommendations in that report.

Mr. TOWNS. Let me ask you this, Dr. Walker. I am sure you have heard it.

There are a lot of folks around that say FDA needs to get its act together; why would you give them something else, when they have not done what they have been asked to do well.

How do you respond to that?

Dr. WALKER. I think we can always respond to anecdotes where the FDA may not have lived up to its total mission. I think if one looks at what has happened in that agency in the last 2, 3 years or so, I think you will see a whole new aggressive movement in that agency. I think they have recruited new people. They have been very, very aggressive in protecting the public from not only food problems but from drug problems.

I would say that a food safety agency, being under the umbrella of Health and Human Services, where there is an opportunity to interact very effectively with the Centers for Disease Control, where the Nation's expertise in epidemiology and all the health sciences is located, I think that would provide an excellent system for addressing some of the problems that you have heard identified this morning.

I think it would then free the Department of Agriculture to focus more attention on this whole range of social and economic problems that are impinging on the American farmer. It would not have its attention diluted or diverted from what is essentially a public health function—from a public health function to these issues that deal with the farmer.

If one looks back to the 1800's when President Lincoln first established the Department of Agriculture, its focus was on agricultural productivity and interest and concern of the farmers. I think much of that focus is still in USDA.

I think the public health aspect is a very small part of the USDA's overall mission. One needs only to look at what is happening in that agency to find evidence that this is an accurate assertion.

Mr. TOWNS. Thank you, Dr. Walker.

At this time, I see the red light is on.

I yield to Congressman Portman.

Mr. PORTMAN. Thank you, Mr. Chairman.

Thank you for holding this hearing and for drawing attention to the issue. I am sorry I could not have been here earlier today to hear all the testimony, particularly from the first panel. I am pleased to be here now. I have also read the statements briefly of a couple of the other witnesses here.

I guess my question really goes to the consolidation issue. It seems to me there is a consensus that—I think there are nine different departments or agencies dealing with food safety. There seems to be a lot of inefficiency in the system. The National Performance Review certainly focused on that issue, the inefficiencies, the overlap, and also the problems of simply not having enough food safety laws that work in many instances, as you heard earlier this morning. I heard Mr. Wilson's statement from the National Cattlemen's Association that a freestanding entity under USDA would be preferable.

Dr. Walker seems to be focused on the FDA role, that the FDA could perhaps under its current organizational structure have a food safety entity that would be broader.

Dr. Menning, I think, taking your cue, I believe partly from your work with the National Performance Review would advocate a freestanding, independent agency under HHS; is that correct?

Dr. MENNING. A freestanding independent agency was the unanimous consensus of our task force. That is not under any department such as the EPA presently is a freestanding agency, not under HHS.

Mr. PORTMAN. So the recommendation that you would have, that the National Performance Review had, was that it would be an independent agency and not under any cabinet agency?

Dr. MENNING. That is correct. That was our task force for the NPR, not of course the overall recommendation.

Mr. PORTMAN. The task force looked at it.

I guess, Mr. Wilson, you could, for me, spell out in some further detail why you think a freestanding entity, without getting into whether it be FDA, HHS, or an independent agency—why that might not work better than having it under USDA when, as Dr. Walker and others pointed out, USDA doesn't have a broad jurisdiction over all food safety at this point?

Why would it be preferable to put it under USDA?

Mr. WILSON. If I understand your original question, it was if, in fact, we would move to an independent agency?

Mr. PORTMAN. Assuming there is a consensus that consolidation is appropriate.

Mr. WILSON. Correct. That may very well be the compromise. I guess from the producers' perspective, we hope, regardless of whether it is at FDA, USDA, or an independent agency, we need to maintain the contact and an infrastructure that supports the producers, the grass roots producers on a daily basis.

That system, just to make a suggestion, if we move all this to FDA, we are simply here to point out that that infrastructure doesn't exist today between producers and FDA as it does between producers and USDA.

If we were to move to an independent agency, we would strongly encourage that mechanisms be put in place that we maintain that communication between producers and the agency. As producers, we feel that we have a vital role in food safety. As research develops and information becomes available to us, we want to use that research and apply it on the farm. Basically what we are saying is that under FDA, we do not have that level of communication that we do under USDA.

So if we are going to develop a new agency, then let's also develop the technology transfer, the producer education systems that we already have under USDA.

Mr. PORTMAN. Dr. Menning.

Dr. MENNING. If I might just reemphasize that, there is a point I wanted to bring out a little earlier. We must all remember that it is the producer's responsibility and then the slaughter plant management's responsibility, et cetera, for maintaining a safe product. It is not FSIS's or any other agencies.

So for a regulatory body to really get the cooperation that is essential, industry must be involved. It is going to be more so with the newer preharvest and other inspections coming into being.

Mr. Wilson is absolutely correct. That structure must remain. But I get the feeling also that people forget that it is not FSIS's responsibility directly for all the food produced. It is the plant owners.

Ms. FOREMAN. Mr. Portman, may I comment on this?

Mr. PORTMAN. Absolutely.

Ms. FOREMAN. I agree it is not the sole responsibility of FSIS, that, certainly, it is the responsibility of the producer and the consumer to prepare it correctly.

But meat and poultry products, unlike any other foods sold in this system, come with a label that says inspected and approved for wholesomeness, U.S. Government. That means there is a special responsibility. I am troubled by the continuation of the use of that seal when we know that products are contaminated with bacteria. We think that because that seal is there it gives a special responsibility because the government has assured the public that the product is wholesome.

Mr. PORTMAN. Thank you, Mr. Chairman.

Mr. TOWNS. The gentleman's time has expired.

I yield to Congressman Payne of New Jersey.

Mr. PAYNE. Yes. Let me just ask you, Ms. Foreman, during your tenure, were there any significant improvements or upgrading in any way of the inspection process, to your knowledge?

Ms. FOREMAN. I think we had some upgrading of the pesticide contamination problem, Congressman. But I will say to you two points, and if I can address something from Mr. Towns' question where I am sure I misspoke: I don't believe that the proposal we put forth in 1978 did, in fact, deal with microbial contamination. It was pesticide oriented. And in the minutes since you asked the question, my recollection is that we were advised—this was 1977—specifically by the general counsel of the Department of Agriculture that we didn't have authority to do the tests that the Booz-Allen-Hamilton study recommended.

This was not an issue, therefore, while I was at USDA; although, it became one near the end of my time there when we had an advisory committee report on salmonella, which I, at first, refused to sign off on because it insisted that this was all the responsibility of the consumer.

The reason that I reference the 1985 NAS report in almost every instance is that that was a seminal report. That is when the Department made a contract with the academy to develop for the first time the framework that a public health-based meat and poultry inspection program should have. All of the preceding reports and a lot of them since then have been directed to how can you—and this was a specific requirement of Booz-Allen-Hamilton—how can you maintain the same level of protection with less money?

The NAS didn't say that, because they said the level of protection we have now is inadequate; how can you make it serve public health better?

It seems to me that that is the point from which we should begin this discussion.

Thank you.

Mr. PAYNE. Thank you very much.

I was listening to Dr. Walker talk about the fact that FDA in the past 2 or 3 years, in his opinion, had improved; and, of course, one of the recommendations that came from the National Performance Review was that food inspection responsibility be transferred and combined at FDA.

You know the whole question of FDA, and one of the problems I have anyway with some of the Federal agencies is that it seems politics sometimes get involved in the function of that agency.

As you may recall—and I had serious problems with FDA because there were a number of problems, the whole question of off-label uses of drugs, which was never really dealt with by FDA; the problem with Retin-A, collagen, their tests with tamoxifen, where there were clinical tests done shabbily where people were not really informed about the side effects and potential dangers of participating in the trial.

The Quayle Council on Competitiveness, that was strictly a political group to speed up the approval of drugs; and they say 9, 10 years takes too long, push them out in 2 or 3 years.

So I guess my point is the lack of movement on silicon implants. We had to push the FDA into really confronting that whole problem.

Maybe this is for anyone: Do you think that I am being overly critical of the agencies?

Second: Do you feel, in your opinion, that politics gets involved and a philosophy prevails for an administration rather than the true function of that agency, what it was intended to perform?

Dr. WALKER. I think your comments are on target. I think it is fair to say that there have been occasions when political influence has impacted upon an agency's effort to carry out its mission. I think it is also clear that ideological directions or bent has certainly been a factor in overregulation, versus deregulation. I think that it permeated the system.

But I would suggest to you that a very objective analysis, a very incisive look at the FDA over the past 2 to 3 years would indicate

that that agency has moved forward. I think many of the issues that you cite are examples of what happened a number of years ago under a different set of administrators. But I think, under the current administration, I see no reason why this cannot continue. I think it is fair to say FDA has been an aggressive agency. I think it is constantly trying to improve its effort to protect the public. And I would suggest that if the move is made, that the Congress would want to exercise very stringent oversight and call the administrator, the Secretary of Health and Human Services to account for what happens in the agency.

One of my concerns—one of our concerns at the American Public Health Association is that we not try to create a whole new bureaucracy, recognizing that there is a shortage of epidemiologists and other scientists to carry out this mission.

One of the advantages of moving this system into the FDA is that in the Health and Human Services structure, there is a good cadre of scientists; the Centers for Disease Control has one of the most effective groups of infectious disease specialists anywhere in the world.

So, I think that bringing these agencies together where there is effective interagency cooperation, I think would benefit the American people in the long run.

Dr. CRAWFORD. I would like to respond to a couple of things you said. I served at both FDA and USDA. I love them both. Your question about: Do politics get involved? The answer is, yes. And a certain amount of that comes from the Congress.

Then the other thing I would like to say is that about the efficiency in the approval of drugs, all that, you mentioned sometimes it takes 8 or 9 years. There are two ways to look at that. One is the Congress when they wrote the act did give the agency only 6 months to approve the drugs, 180 working days. When they go past that, they technically are in violation. That either ought to be enforced in my view or changed. If it is a lifesaving drug, the longer it is kept off the market, provided it is safe and effective, you know it actually does cost human lives.

You also mentioned off label use of drugs. I suspect you mean veterinary drugs. As you know, extra label use or the physician's discretion is allowed with human drugs but not allowed technically by the law because of an omission—I think not a commission on the part of the writers of the law—is not allowed for veterinarians.

That is something that I believe is before the Congress now and, in my view, needs to be corrected. You will never have enough drugs for human medicine or veterinary medicine, dentistry, or anything else to treat all those drug amenable conditions that are out there. Failure to allow it, I think, does cost lives and cost causes problems.

Ms. Foreman mentioned the effectiveness we have had in dealing with the pesticide residue problems in milk, meat, eggs, and everything else. That is certainly true. It started in those years she mentioned.

We have also had enormous good luck in reducing the amount of antibiotics, other chemicals, lead, these sort of things. They are now down to the lowest level just about imaginable. So there have been some successes, I think.

Mr. PAYNE. Yes.

Dr. MENNING. A comment on political influence: That is definitely yes. But that is in a very broad sense. Because there is political influence from Congress that can be adverse, say, on closing the meat plant or something; a congressional person from that area, et cetera. But it goes much further than that. There is great political influence from Ms. Foreman and her Safe Food Coalition that either impedes or slows down or could add to, one way or the other, whatever it is, of political appointees, assistant secretary, et cetera, who don't like to take the heat.

When persons come up with let's evaluate the microbiological worth of meats, this is going to raise a lot of hackles in industry and everything else. People are going to find out there is disease there. Political appointees themselves put the kibosh on things such as that.

Then you have, finally, also the political influence from the unions which is an extremely powerful thing that can delay, procrastinate, or add to and help.

But all these political influences are encumbrances on any administrator that just makes it a very undesirable job.

Mr. PAYNE. OK. Thank you very much.

Just let me ask one last question. The chairman always says something about the red light. I didn't have my glasses on, so I didn't see it.

Dr. Menning, as a veterinarian, in your opinion, how great is the risk of contamination from our current supply of products, meats, out there?

Dr. MENNING. I don't know. No one really knows. It depends on what you want to specify it for. If you want to say how great is the risk for all pathogens and disease organisms totally, then I have always, in my speeches and papers and with data to back it up, tell everyone they must presume every raw piece of meat and poultry they buy to be contaminated with a disease-producing agent.

All studies have shown in the neighborhood—when you count them all: salmonella, campylobacter, E. coli, listeria—you count them all, you are getting at or near 60 percent or above findings. When you have 60 percent or above findings in your retail meat case, you count them as all.

Now when you get down to the E. coli, that is really the driving force running this fast train down an unknown track in the past few months, the risk is not nearly that great. However, it is a very risky disease which then makes it assume a greater status than its numbers would normally indicate.

But foodborne disease is not the greatest public health problem by any means. But it is great enough that it deserves more attention than it has had for many years and should be getting now.

Mr. PAYNE. Thank you.

Really the last question, Mr. Chairman.

Dr. Walker, do you feel that there is enough direction from the Federal Government of, down to local governments, for example, everything is just fine when it leaves the Federal inspectors' jurisdiction and gets down into a city where perhaps a town, the refrigeration is bad, or the place is not clean.

How much direction—since I believe you were formerly a health director for the city of Newark, NJ, how much direction comes down from the Federal Government to a local health department that says you should have X number of inspectors; you should have X number of meat inspectors for the city? What kind of direction is given to local governments and State governments?

Dr. WALKER. I think through the Department of Health and Human Services, Centers for Disease Control and FDA, there has been a fairly good working relationship. I think that the short-term training courses, the guidance documents that comes from the Federal level down to the local level, I think, are fairly good documents.

But I think it is important to point out here that, in public health, we follow what we call a principle of multiple barriers in which we try to build barriers between the source of contamination, if you will, and the consumer.

So in our view, barrier No. 1 is to reduce the pathogenic load upstream, meaning at the processing plant, et cetera.

Barrier No. 2 is obviously adequate refrigeration.

Barrier No. 3 is, at the consumer level, adequate cooking.

All of those barriers, in our view, the American Public Health Association, are very, very important.

I think it is also important to add here that many of the bacterial contaminants that are passed on to consumers do not manifest themselves in disease in the organisms. We are not convinced, based upon some of the microbiological epidemiological data, that the E. coli manifest itself in infections or sickness in the animal. But it does manifest itself when it is consumed by the public.

So I think all of these factors have to be taken into careful consideration. But I think there is a very good working relationship between the Federal Health and Human Services group, which has as its constituency State and local health department departments.

This does not, in my view, answer the problem of multiple inspections where, in some States, there is a problem of Agriculture going in, the State Department of health goes in, the local department, multiple inspections. That, in my view, frustrates the business community.

Mr. PAYNE. Thank you, Mr. Chairman.

Mr. TOWNS. Thank you.

The gentleman's time has truly expired.

Let me just, for concluding, ask you this question, Mr. Wilson—I tried not to ask this, but I can't let you go without asking it.

You indicated that since 1988, that your agency has been asking USDA to improve its inspections. Why doesn't the companies or the industry improve inspections? Why don't they move to make some changes themselves?

Mr. WILSON. In many cases, Mr. Chairman, they have. Many of our top meat packing plants have developed their own HACCP programs and quality control programs. Not all. But we do have those shining examples of good plants doing an excellent job in microbial reduction and monitoring and control.

The beef cattle producers themselves, since 1988, have spent over $1 million specifically on E. coli 0157:H7 research. Unfortunately, we do not have all the answers. What we are finding is the more

research we do, the more—the less we know. That propagates more research.

So there is a lot of effort on behalf of the industry to get at this problem. In 1987, the NCA met with the Centers for Disease Control. We asked them—in developing a beef quality assurance program that our producers could grab hold of, we asked them what we should be looking at from a food safety standpoint. They told us that basically, given current interest in chemical residue at the time, that does not present a human health risk.

Your problem is microbiological contaminants, and specifically E. coli 0157:H7. As a result of that meeting, we established immediate policy asking for research and development, diagnostics, and controls for E. coli. As producers, we started to fund projects with two or three different universities, specifically on E. coli 0157:H7.

There is a lot that has been done. Unfortunately, we do not have all the answers.

Mr. TOWNS. Let me thank all the witnesses. We really appreciate your testimony and your taking the time to come and be with us.

I would like to ask unanimous consent to include additional material in the record from the American Meat Institute and others.

Without objection, so ordered.

[The prepared statement of Mr. Boyle follows:]

For Record

Statement of
J. Patrick Boyle
President and CEO, American Meat Institute

House Committee on Government Operations
Subcommittee on Human Resources and
Intergovernmental Relations
November 4, 1993

Much has been made in recent months of the disparity in government food inspection programs. For example, for every dollar spent to inspect meat and poultry by the Food Safety and Inspection Service, only 12 cents is spent to inspect the remainder of the food supply by the Food and Drug Administration. For every FDA food inspector, the Food Safety and Inspection Service employs eight meat and poultry inspectors. And for every plant inspected by FSIS, FDA inspects three.

In sum, FSIS inspects one-third the food plants with eight times the budget and eight times the staff. More than one million taxpayer dollars are spent every day to inspect meat and poultry products.

Meanwhile, CDC statistics show that only one-fourth of foodborne illness outbreaks result from the products FSIS inspects. Furthermore, those statistics indicate that 77 percent of foodborne illness outbreaks are triggered by mistakes made in commercial kitchens -- a link in the food chain monitored to varying degrees by state and county health departments, with oversight from FDA.

Vice President Gore's "Reinventing Government" report highlights some of the regulatory problems and inconsistencies that result from the current inspection programs at FDA and FSIS. It observes that meat and poultry products must be inspected daily, while shellfish, which have the same risk of causing foodborne illness, are not required to be federally inspected at all.

With respect to enforcement, the report points out that if FDA finds unsanitary conditions or contaminated products, compliance is usually voluntary because the agency lacks FSIS's power to close plants, withhold inspection or detain suspected or known contaminated products. And if one agency refers a problem to another, follow up is at best slow and at worst ignored.

The report also notes that there are no fewer that 21 agencies engaged in research on food safety, often duplicating each others efforts, and that we not progressing fast enough in understanding and over-coming life-threatening illnesses.

The report correctly points out that USDA relies primarily on inspection by touch, sight and smell. It calls for more modern and reliable methods based on science.

Under the report's recommendations, the FDA would handle all food safety regulations and inspection, spanning the work of the many different agencies now involved. The new FDA would have the power to require all food processing plants to identify the danger points in their processes in which safety inspections would focus. Where and how inspections are carried out, not the number or frequency of inspections, would determine the efficiency of the system.

The FDA would also develop a rigorous, scientifically-based system for conducting inspections.

The report concludes by stating that we should employ the full power of modern technology to detect the presence of microbes, giving Americans the best possible protection. Whenever possible, reporting should be automated so that high risk foods and high risk food processors can be identified quickly. Enforcement powers should be uniform for all types of foods with incentives built in to reward business with strong safety records.

Whether or not the recommendations from Vice President Gore's report are acted on with respect to consolidating inspection at FDA - this report could provide a blueprint for modernizing and improving our approach to food safety and food inspection. At a minimum, it should also serve as a wake-up-call to USDA's Food Safety and Inspection Service, encouraging the agency to accelerate the process of inspection modernization, proceed with their Hazard Analysis and Critical Control Point (HACCP) initiative, and shift their emphasis from inspection to prevention.

Preventing foodborne illness is only one component of federal food inspection programs, but it is the most important part. The entire debate over "Reinventing the Federal Food Safety System" centers not on where our programs are headquartered nor who has jurisdiction, but on preventing public health hazards.

If we truly intend to move forward with a more effective Federal food safety system, then all affected parties must agree on one point: let science drive the issues and the reform initiatives. Only science can break the gridlock.

For too long, labor, consumer groups, government and industry have deadlocked over issues having nothing to do with public health. Entire food safety bills have been derailed over such things as whistleblower protection, which has nothing to do

with protecting consumers' health.

NAS Report on Meat and Poultry Inspection

If the recommendations in Vice President Gore's report on reinventing government sound familiar, it is because they are not dissimilar from the recommendations cited in a 1985 report from the National Academy of Sciences and from similar recommendations from industry groups, including the American Meat Institute.

In its 1985 study on meat and poultry inspection, NAS recommended that USDA's Food Safety and Inspection Service develop a Hazard Analysis and Critical Control Point, or HACCP, approach to monitoring food safety.

The NAS Study generally concluded that:

• Consumers have a high level of confidence that meat and poultry products are safe and wholesome.

• That new programs and procedures instituted by FSIS in slaughter and processing areas are unlikely to reduce those aspects related to public health protection, however, such changes need to be well-defined in terms of relevant public health issues.

• And that there is a positive willingness to change at USDA/FSIS in order to provide short and long range policy management systems that accommodate new technologies.

In order to effectively implement these conclusion, the NAS study recommended that:

• Personnel skills within FSIS management should reflect an interdisciplinary concept such that not one profession (discipline) is dominant.

• That policies and programs should more adequately reflect what is and is not "critical" in terms of public health risk.

• And that these programs should clearly focus on identifying the source and risk of potential problems and establishment of management systems for prevention at the source.

NAS encouraged FSIS to apply HACCP concepts to each and every step in plant operations and all types of enterprises involved in production, processing, storage and ultimate utilization of meat and poultry products.

NAS said hazards should clearly be defined as those associated with public health risk. By focusing on hazards and control points related to public health concerns over those which

are aesthetic and unrelated to public health, FSIS could attain the highest degree of public health protection within available resources.

Continuous inspection is not needed to ensure food safety in meat and poultry processing plants in which critical control points have been identified and are being controlled and monitored by a qualified staff. The NAS report stressed that the identification of critical control points is the very foundation for constructing any modern quality control system.

One problem with traditional meat and poultry inspection is that an inordinate amount of time and effort is spent on relatively minor deficiencies which have no relation to public health risk or economic adulteration. This wastes precious resources and puts public health at risk.

Using HACCP principals both within companies and in the Federal meat and poultry inspection system, both FSIS and the industry could direct available resources to the most important problem areas.

Inspection Must Change to Focus on Preventing Pathogens

The 1985 NAS report also stated that "The inspection system is not designed to detect human pathogens unless they produce an observable lesion (in animals). This therefore raises a fundamental questions as to what the current inspection procedures provide for the public."

I would like to address the microbial hazards today's inspection system is not designed to detect. First, because they are the subject of much misinformation and misunderstanding. Second, because they pose the more serious public health hazard.

The slaughter and butchering of carcasses is intended to be carried out under sanitary conditions, but they are not surgically sterile. Animals and birds may sometimes harbor microbes on exterior or interior surfaces (as do humans).

But the presence of microbes does not necessarily indicate health risk. Indeed, any unprocessed food is virtually certain to carry some kind of microbiological contaminant, including fresh fruits and vegetables, milk, eggs, and grains.

Human illness occurs only if the microbe reaches the human body in numbers adequate to cause infections, and at a time when biological defense mechanisms are unable to respond to the challenge. With proper slaughter, processing and distribution; careful food handling in homes and restaurants; and adequate cooking, the microbial risks of meat and poultry to the consumer are close to zero.

Conditions are not always perfect, of course, and one may ask whether today's traditional "organoleptic" meat and poultry inspection (by sight, touch and smell) can adequately protect the public. The answer is no, not to any appreciable degree.

The microbial contamination that leads to human health risk is not sufficient to make slaughtered birds or animals visibly ill, and in most cases makes up only a tiny fraction of the total microbial burden. That burden as a whole is simply not generally detectable by organoleptic inspection.

This should not surprise us. The human body, too, is covered with countless microorganisms, some of which are capable of causing disease if they get past the skin. But those microorganisms cannot be seen, of felt, or smelled--and they usually cause no trouble.

Shortcomings of Traditional Meat and Poultry Inspection

In summary, traditional organoleptic inspection of freshly slaughtered meat and poultry has almost nothing to do with the protection of human health.

I believe that the focus on animal disease detection and the lack of focus on human pathogens is the most significant flaw in USDA's inspection philosophy and has been the root cause of much of the negative publicity and lack of public confidence that finally resulted in the Vice President's recommendation to eliminate FSIS as a separate agency.

Simply moving FSIS to another agency, however, is not the solution. What we need is not reorganization. What we need is a new system that is science driven.

Last February Agriculture Secretary Mike Espy outlined a two track program to modernize the inspection system and reduce the incidence of pathogens in raw meat and poultry. This pathogen reduction program is consistent with the NAS recommendations and the philosophy outlined in the Vice Presidents' report. Industry supports most of Secretary Espy's recommendations.

We supported in principle two components of the FSIS plan - zero tolerance for visible defects on beef carcasses and safe food handling labels for raw meat and poultry. Unfortunately, due to flawed implementation, these efforts have resulted in millions of dollars in unnecessary cost.

Suggestions for Improvement

In my view, the key for FSIS is to rely more on scientific principles as the agency implements the NAS recommendations and as it responds to sudden events such as the E. coli crisis.

FSIS should move quickly and decisively to implement HACCP and provide an aggressive HACCP training program for inspectors. The recent decision to postpone a proposed rule on HACCP erodes FSIS's credibility.

If FDA successfully implements HACCP for seafood and other FDA regulated products, and FSIS is unsuccessful in implementing a HACCP rule for meat and poultry, consumers and industry will suffer and the pressure to consolidate inspection at FDA will increase. Such consolidation is a non-solution that deflects attention and resources from the real problem.

In addition to successfully implementing HACCP into inspection reform initiatives, FSIS must effectively communicate improvements to the public. Public confidence is vital to the success of government programs. FSIS must restore public confidence in meat and poultry inspection the way FDA has worked to restore public confidence in its regulation of the food and drug industries.

Finally, and most importantly, both USDA and we in industry must deliver on our commitment to make meat and poultry products safer.

How Industry Can Help

AMI and the AMI Foundation have already developed many technologies to control pathogens and are looking to establish more. New technology using mildly acidic carcass sprays and decontamination procedures offers practical means to reduce pathogens.

Other methods of reducing pathogens in meat packing plants include antimicrobial dips, such as the trisodium phosphate recently approved for poultry; more sanitary hide removal, using equipment or chemical treatments to reduce contamination, and the possibility of a final pathogen reducing treatment such as cooking or irradiation.

We also need to look to the farm and livestock production as critical parts of the process where pathogens can be minimized or destroyed. In the poultry industry, for example, growers are trying to breed Salmonella resistant chicks. Probiotics may also be useful in controlling harmful microorganisms in live animals.

As we look further down the food chain through distribution, retailing and handling, there are critical points in the process, including safe storage temperatures to prevent microbial growth, and observing safe cooking temperatures.

This Administration has stated its commitment to change the way government works -- including the way meat and poultry are

inspected. The meat and poultry industry supports constructive change -- but not change simply for the sake of change.

We must move forward in developing science-based initiatives, including HACCP, to improve the safety of meat and poultry products.

11/93

Mr. TOWNS. I ask unanimous consent to hold the record open for 10 days to allow other interested parties to submit statements for the record.

Without objection, so ordered.

This morning, we heard very disturbing news about the lack of progress in USDA in making reform. We will hold USDA fully accountable at our hearing on November 19.

At this time, the subcommittee will adjourn.

[Whereupon, at 12:40 p.m., the subcommittee adjourned, to reconvene on Friday, November 19, 1993.]

REINVENTING THE FEDERAL FOOD SAFETY SYSTEM
(USDA's Progress in Reforming Meat and Poultry Inspection—Continued)

FRIDAY, NOVEMBER 19, 1993

HOUSE OF REPRESENTATIVES,
HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 2247, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the subcommittee) presiding.

Present: Representatives Edolphus Towns, Thomas M. Barrett, Donald M. Payne, Steven Schiff, John L. Mica, and Rob Portman.

Also present: William M. Layden, professional staff member; Martine M. DiCroce, clerk; and Martha B. Morgan, minority professional staff, Committee on Government Operations.

Mr. TOWNS. The subcommittee will come to order.

On November 4, 1993, this subcommittee listened to a mother tell us how her 3-year-old son painfully died as a result of eating meat contaminated with E. coli 0157:H7, a deadly bacteria. We listened to two other mothers tell us about how their children have also suffered because of E. coli infections. Sadly, we learned that Scott, Brianne, and Damion are just 3 of the 20,000 people that the Centers for Disease Control and Prevention estimates are infected each year with E. coli 0157:H7.

Overall, more than 80 million foodborne illnesses occur each year in the United States, according to CDC. And the problem is getting worse.

Several witnesses testified that E. coli 0157:H7 and other deadly bacteria easily escapes USDA's current visual inspection approach because inspectors cannot see, smell, or feel microbial pathogens that cause nearly all cases of foodborne illnesses.

Witness after witness testified about USDA's pattern of failure to act. Mr. Harman from GAO said, "I think it is an understatement to say USDA has not responded to these increased risks despite being on notice since at least 1977 about the need to revise the system."

Many of the witnesses blamed USDA's failure to act on the inherent conflict of interest in USDA's dual mission: to promote agriculture and to protect the consumer. They stated that this conflict is irreconcilable.

Earlier this year, Agriculture Secretary Mike Espy recognized the dangerous flaws in USDA's programs and announced a series of initiatives which I applaud. However, several witnesses stated that USDA is not making acceptable progress. Among other things, they cited problems with USDA's proposal to mandate safe handling labels and delays in the department's development of needed legislative proposals.

Today we will hear directly from USDA about the progress it is making to reform its meat and poultry inspection programs. But the American public wants more than promises of reform. The public wants immediate action. Children are dying because of bureaucratic inaction.

The fundamental question before this subcommittee today is whether the American public is better protected from deadly bacteria in meat and poultry today than it was in January of this year or even in 1985 when the National Academy of Sciences concluded that USDA's inspection programs were inadequate.

The haunting words of Susan Kiner, whose daughter continues to suffer from E. coli poisoning, still echo in my ears, as she said, "Have you ever planned a child's funeral?" This country must act to ensure that meat and poultry products are safe to eat and not plan funerals for our children who die because we failed to act. This is unacceptable in one of the richest countries in the world. It is unacceptable.

At this time I yield to the ranking member of the committee, Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. I will be brief.

I want to, first of all, commend your leadership for continuing this very important set of hearings.

I was struck in the last hearing by a feeling very much like information that we have all received about the development of AIDS in the sense I realize we don't have that situation here at the present time, but some of the substantive testimony that we had in terms of the E. coli infections sounded very familiar.

First, it is an infection that was almost unheard of with this particular strain of E. coli, if I understand the testimony, until a relatively few years ago.

Second, it can be deadly in terms of its effect. It has been deadly. We have heard that all too clearly in the testimony.

Third, although there was not a lot of emphasis on this, again, if I understood the medical testimony, this is a communicable disease, that is, siblings and so forth can infect each other with this disease. It is not simply a matter of the only individual who can be infected is the individual who consumed the meat that was tainted.

So I see the development of an epidemic coming that will affect the citizens of this country in more than the unfortunate relatively few cases we have already seen in the relatively near future if we don't do something about it, and I want to say that my observation is that the U.S. Department of Agriculture, from what I have seen so far and I know they will testify before us, has not sufficiently addressed the urgency of this problem, and that is no partisan comment.

I think the evidence is that well back into the Bush and Reagan administrations enough information was there to have seen the U.S. Department of Agriculture take further action.

Now I have to say though, under the new administration, I am not sure that we have seen any more progress, and I am very concerned, Mr. Chairman. This might seem like a technicality, but I am informed that we received the testimony, the written testimony of the U.S. Department of Agriculture officials, at about 7 p.m., last night, which was, obviously, too late for the staffs to go through it, analyze it and adequately prepare the normal questions for us.

And that concerns me not just because of the hour but I wonder if that is not representative of what is going on over at the USDA. I wonder if they aren't scrambling to say something to the Congress while this problem threatens to turn into epidemic proportions.

So I want to say that I again appreciate your having this hearing, and I want to say to the USDA, under the present administration that this committee stands ready to work with you to help you. We have a common problem here. Nobody is against anybody, and we would very much like to hear your ideas, and I would very much like to be corrected in my impression. And if I am not corrected, what can we do together to turn the situation around?

Thank you, Mr. Chairman, I yield back.

Mr. TOWNS. Thank you very much, Congressman Schiff.

At this time, I would like to call on our first witness, Congressman Robert Torricelli from New Jersey. Good morning, Congressman.

STATEMENT OF HON. ROBERT G. TORRICELLI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. TORRICELLI. Thank you, Mr. Chairman, Mr. Schiff, and thank you for the opportunity.

Mr. TOWNS. Welcome you to the committee. Let me say that your entire statement will be included in the record: every I, every question, every T, every whatever you submit will be included in the record. We would like for you to just proceed any way you wish but letting you know that your statement will be included.

Mr. TORRICELLI. Thank you very much, Mr. Chairman, and let me first commend you for having this hearing. It is a message that the entire Congress needs to hear and would not had you not taken the leadership in calling this session today.

I would like to introduce the committee to the issue of bacterial infections in food much as I was introduced to it and it appears as you were introduced to it. Only a few months ago, I met Arthur O'Connell of Kearny, NJ, a small town in my own district, who on one Saturday afternoon brought his 23-year-old daughter, Katie, to a movie and then, like millions of other people on afternoons across America, brought her to a fast food restaurant for lunch. Less than 3 weeks later, after organ by organ in her little body deteriorated and stopped functioning, she died. The cause of her death was Hemolytic Uremic Syndrome, E. coli bacteria in a simple hamburger.

Almost until the moment of her death, the doctors who cared for her didn't even know what she had, and, mostly, she never had a chance. At first, I thought I was hearing about some extraordinary

rare illness that by some freak of nature reached out and struck one little child in New Jersey. Only later did I come to learn that 9,000 people a year in the United States die from some kind of bacteria in the food they consume.

If the American people even began to understand that there was an epidemic of this kind of proportions, they would be all over this capital to every Member of Congress. Somehow in silence family after family has been struck thinking that they alone or they with a few people have been victims of some extraordinary misfortune.

9,000 deaths isn't a freak of nature. It is a colossal public health failure. Katie O'Connell may have brought this to me, but one by one similar cases are going to bring this crisis to every Member of Congress in every community of this country unless something and something soon is done.

The Jack in the Box tragedy in Washington State has prompted USDA to announce new cooking and safe food handling labels for meat and poultry. I am glad something is being done because I think this committee recognizes it is only a very small beginning, and the problem begins in the USDA itself.

We have given to an agency of government both the mission to promote the sale of agricultural products, to increase production and to promote public health and safety and inspection. It is an inherent conflict of interest, and it cannot be resolved within the USDA.

As Vice President Gore has noted in his report in reinventing government, it is best solved by removing this responsibility from the USDA. There should be in a public health agency of this government the responsibility of promoting the public health, creating a conflict with the USDA, not within it, by insuring there is someone in an adversarial position.

For several months, Mr. Chairman, I have been working on comprehensive legislation, working with the victims of these diseases, other agencies of the government, to write comprehensive legislation to reform the inspection process. It will be completed soon ready for your review in January when we return.

The most important aspect will, obviously, be to remove this inspection process from USDA, but that is not all. There are several other important aspects of reforming this process. The most important is the technology itself.

I can recall in college as a student in reading Upton Sinclair the extraordinary story of how Americans died by the thousands because early in this century there was no inspection. Most Americans would be shocked to learn that the answers that came from that revolution in public health, the technology generations ago, is the same technology we are using today for public safety: the human senses.

Federal inspectors who are the only line of defense between the public and these bacterialborne diseases use their eyes, their noses to protect against contaminated food. If I hadn't seen it, if I hadn't read it, if I hadn't inspected it, I wouldn't have believed it myself. A government which sends spacecraft to the planets of the solar system with sensitive instruments to measure temperature sends inspectors into meat plants with their eyes, ears, and noses. A government which measures every nuance in changing weather condi-

tions, senses slight tremors in the ground for earthquakes with the most sophisticated instruments ever invented, and this is how we review meat coming off assembly lines to protect our citizens?

It would be a miracle if it were not failing, and it is failing, and the only extraordinary result is that nothing has been done about it.

And so, first, Mr. Chairman, is the requirement that there be the usage of the very best technology to ensure that meat and poultry that we are consuming on the assembly line, during production, is safe at every stage.

Finally, Mr. Chairman, it will be my own recommendation that we also implement in the food industry on a retail basis those things which we simply know offer some real protection even if contaminated meat and poultry make their way to restaurants and stores, and that is simply higher levels of heat. Part of the reason why this problem is accelerating is more and more Americans are eating fast food. More and more of it is produced by people who do not take the time or have the knowledge to know how to prepare the food, and so much of it is inadequately cooked at insufficient temperatures.

At a minimum, we should be requiring and enforcing that every fast food restaurant in America meet a minimum temperature requirement to kill these bacteria before they can reach our citizens.

I will do my best to produce a product, together with other Members of Congress, so this committee can do its work. I know the committee itself as a result of these hearings will give that same attention.

These, Mr. Chairman, are only a few suggestions of many that will come forward to deal with this problem, but it must be dealt with comprehensively, quickly in a way that leaves no suggestion unanswered. This, Mr. Chairman, in a time when there are so many problems we cannot solve, tragically so many illnesses for which science does not have the answer, this is one where we do have the answer. Every death is unnecessary. Every month that goes by did not have to be.

This committee, this Congress, can insure that there are no Katie O'Connells, that every parent who walks in a restaurant in America can do so with assurance, with confidence and safety that they are not placing the life of their child in danger because they took the extraordinary step of buying them a hamburger on some Saturday afternoon.

Thank you for this opportunity, Mr. Chairman, and I appreciate it and the committee's attention.

Mr. TOWNS. Let me thank you, Congressman, for your statement, and we look forward to working with you to bring about a solution to this problem. I agree with you that we do not need anymore Katie O'Connells, and I think that your very thoughtful testimony sort of reminds us of that.

[The prepared statement of Mr. Torricelli follows:]

TESTIMONY ON MEAT AND POULTRY INSPECTION

HON. ROBERT G. TORRICELLI

GOVERNMENT OPERATIONS SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL OPERATIONS

NOVEMBER 19, 1993

Thank you Chairman Towns, members of the subcommittee, for holding this hearing and for allowing me the opportunity to testify.

The issue of meat inspection is one of life threatening proportions. An estimated 9,000 Americans die each year from bacterial foodborne illness. That is far, far too many for a nation that prides itself on having one of the world's safest food supplies.

Tragically, the problem is growing worse. The reliance of Americans today on fast foods and re-warmed foods has led -- and will continue to lead -- to an increased number of food poisoning cases.

My interest in this issue intensified two months ago, when Safe Tables Our Priority held a Congressional symposium on foodborne illness. It was then that I had the honor of meeting an extraordinary man, Arthur O'Connell.

Mr. O'Connell is a constituent of mine from Kearny, New Jersey. He is a dedicated family man and a hard working high school mathematics teacher. One day, Mr. O'Connell's 23-month-old daughter, Katie, did what millions of other children across this country do every day -- she ate lunch at a fast food restaurant. Less than three weeks later, after a horrible illness that attacked each of her organs one by one, Katie O'Connell died. The cause of death was Hemolytic Uremic Syndrome, an illness caused by the presence of E. Coli bacteria in the hamburger she ate.

With no warning, and with no opportunity for prevention, the O'Connells lost a healthy and vivacious toddler. Few events in my eleven years in Congress have moved me so deeply as Artie O' Connell's testimony and my later conversation with him. We can, we must, and we will do better.

This committee recently heard several other emotional stories of families whose lives have been shattered by foodborne illness. These stories represent an inexcusable failure of government. Indeed, while I have been part of hundreds of debates on the proper role of government, nobody can disagree that one thing we can and must expect from our government is a safe and healthy food supply.

In the wake of the recent Jack-in-the-Box tragedy in Washington State, the United States Department of Agriculture announced new cooking and safe food handling labels for meat and poultry products. I commend the Department for doing something, but it clearly is not enough. We must ensure that every precaution is taken and every technology is utilized to ensure that the food products delivered to our grocery stores are safe.

Indeed, perhaps the biggest problem is that the Department of Agriculture has not, and cannot, properly perform its mandate. Congress has directed the USDA to increase agricultural production and to promote the sale of agricultural products. It also directs the USDA to promote and protect the public health by rigid inspection of meat and poultry products. This is an inherent conflict of interest.

Vice President Gore has recognized this conflict and has recommended moving meat and poultry inspection responsibilities out of USDA and into the Food and Drug Administration. While I do not agree that the FDA is the best place for these responsibilities, I completely agree that the time has come to move meat and poultry inspection to an agency that is dedicated first and foremost to protecting the health of American consumers. A public health function is best housed in a public health agency.

When we return in January, I will be introducing comprehensive legislation to reform the meat and poultry inspection process. The most important feature of this bill will be creation of an independent agency, staffed by public health experts and dedicated to promoting the public health, to oversee meat and poultry inspection.

This bill will also address the sorry state of technology in the meat and poultry inspection field. Currently, there is a surprising and dangerous lack of scientific-based testing involved in the inspection process.

Amazingly enough, USDA food line inspectors use the same tools in 1993 to detect the presence of microbacterial infections that they used in the days of Upton Sinclair -- their senses. That's right -- despite a 1985 National Academy of Sciences report that urged the USDA to develop and implement rapid, online tests for bacterial contamination, USDA inspectors today use only their sight, touch and smell to inspect meat and poultry products.

It has been over eight years since the NAS report, yet the USDA has made virtually no progress in development of these tests. It grieves me to wonder how many lives could have been saved if the USDA had acted upon these recommendations.

I have heard allegations that the science is not available to develop these tests. I do not pretend to be a scientist, but I am a member of the Science, Space and Technology Committee. And I must question why a government that can develop a "smart bomb" cannot develop technologies to test for meat and poultry contamination.

My bill will not stand for this appalling lack of progress. It will direct immediate research and development into a rapid, on-line microbacterial testing system, as recommended by the NAS in 1985.

Finally, my legislation will direct the Center for Disease Control and the National Institutes of Health to gather information on foodborne illnesses and develop standard care procedures and treatment for these illnesses. Almost as shocking as the frequency of foodborne illness in this country is the lack of medical knowledge on how to treat it. This is another area in which we can and must do better.

I am hopeful that members of this subcommittee will join me in introducing this important legislation. Improved meat and poultry inspection will not completely eradicate outbreaks of illness caused by foodborne bacteria. But there certainly can be a great deal of improvement, and there is certainly the potential to save many lives.

Thank you again for the opportunity to speak today. I look forward to working with the subcommittee to make sure that Congress enacts real changes in our meat and poultry inspection system in this session. Inefficiency and ineffectiveness in this vital area can no longer be tolerated.

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Mr. TOWNS. At this time I would like to yield to Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. I want to thank our colleague for your testimony and for your leadership in this issue.

I would like to say, you may or may not be aware of it, but we asked the group of parents who have been through this with their children what they—what solution they see, and one of the parents said exactly what you said. And they clearly have spent a great deal of time looking at this issue, which is very understandable, that they believe that there is an inherent conflict of interest in the U.S. Department of Agriculture, which is no insinuation against any individual who works there, but that a program designed to foster the sale of meat products produced in the United States has some inherent reason not to alarm people with health warnings about that same product. It is an institutional conflict of interest.

The more I hear, the more I am persuaded that is the case, but I wonder, where would the—where would we place the food inspection—if we took the food inspection responsibility away from the U.S. Department of Agriculture, I think the Vice President suggested putting it under the Food and Drug Administration. That is my recollection, and I have heard some criticism of that idea just because the FDA is a research more than it is a practical, on-the-scene kind of agency, so I would like your opinion. If we do move the food service inspection responsibility, where would you put it?

Mr. TORRICELLI. I think the Vice President's idea that he said there should be an agency that is a public health agency, his suggestion was the public health agency be under the FDA. There may be other places in the Federal Government. I think which department in which it lies is less important than the concept that there be an adversarial relationship.

The USDA measures success or failure in terms of whether the American people are consuming these products and have confidence in the food supply. I don't want them to have confidence in the food supply. I want somebody to be ringing alarm bells, because that is what moves this government to solve problems and people to bring public pressure. That is why this is not only a problem because 9,000 people are dying. It is a problem because 9,000 people are dying, and people don't even know about it.

I leave to the committee the judgment where this public health agency should rest. It is simply my conclusion that there should be one.

By the way, I want the committee to know, we have focused on the 9,000 deaths. As you meet with more and more of these families, you will find, in addition to the deaths, how many children became blinded, deaf, paralyzed. This bacteria does not often kill. Sometimes when these children die, it is merciful. It robs them of their senses and the life of their limbs.

Mr. SCHIFF. I yield back, Mr. Chairman.

Mr. TOWNS. Congressman Mica.

Mr. MICA. Congressman, I thank you for joining us today, and I appreciate your dedication and personal commitment to this effort. But I am wondering if, in fact, that you may be trying to create an end result which is very expensive, costly and may not really address all of the problems that we have seen here.

One of the problems you have—I mean, just the simple logic of—and process of cooking hamburger, we found that the major problem is not enough heat and, you know, you have advocated using the best technology, and I think we have got some proposals to try to upgrade the technology from the department, but I am really wondering, there is a human factor here. You can put all this together, and you are still going to have incidences where people don't follow instructions, follow good practices, sound healthful practices. So I am wondering if we are sort of just tilting at windmills here.

You know, there is nothing worse than seeing a child suffer or a life lost, but you are talking about cooking—I haven't been by the McDonald's sign lately to see how many are cooked, but that is just one instance. And all you have to do is have someone not follow instructions, and you can have the incidence that we have seen. So I am wondering if this is a sort of overkill.

Mr. TORRICELLI. Well, there is something, Mr. Mica, that is worse than a child dying and suffering from this disease. It is a child dying and suffering from this disease knowing that it didn't have to happen, and then that the government that was elected to care for them didn't do anything about it.

So I would submit to you this is a significantly more serious problem than the one you just suggested.

It is unnecessary because, in my judgment, the technologies of inspection are available. Having an assembly line where we are deciding whether or not meat is safe because an inspector sees it come down the line and says, that looks OK, walks by a piece of meat and smells it and says, well, that smells fine, that is the inspection system of the U.S. Government.

Mr. MICA. Are you aware of the report of the E. coli 0157:H7 outbreak from the U.S. Department of Agriculture dated May 21, which, in fact, said that there is no rapid test that can be performed on either raw meat or poultry to detect the presence of microbial contamination.

Mr. TORRICELLI. If you allow me to answer the question, are you prepared to accept that that is a final result, and we either can't or shouldn't try to find one?

Mr. MICA. Well, I don't have a problem with trying to find one, Congressman, but, again, even if you perform this rapid test, and we create the technology to do it and then the meat is contaminated somewhere—there are so many steps in handling, there are so many steps in preparing. There is the possibility of mechanical breakdown even if we had equipment that seared the hell out of hamburger, that, again, I am saying that we can't create these systems that are fail safe, and you have to look at the costs, and you have to look at the risk.

It is unfortunate that one child has died and many others, but I submit, too—I mean, automobiles, look how many children are killed and maimed by automobiles.

Mr. TORRICELLI. Yes, which did not stop us from moving forward on auto safety. No one ever argued that we were going to save everyone in an automobile accident.

Mr. MICA. They are still on the street and running people over.

Mr. TORRICELLI. So should we not have had air bags or safety belts or shock-absorbing bumpers?

Mr. MICA. I agree, but I just think, again, we have to look at how far we can go with some of these things. We can create tests—I mean, you create a test when the meat is in the slaughter house, which we already do, and maybe some of the olfactory senses or people that are in this can tell by color, smell and other things as well as the most sophisticated machine.

Mr. TORRICELLI. Mr. Mica, if they did, 9,000 people wouldn't be dying. Apparently, somebody's nose isn't working well.

Mr. MICA. But Congressman, what is it at that stage that the contamination took place? Or was it when it was shipped from the slaughterhouse? Shall we test it again as it goes in a refrigerated truck or train or something and then, from that point, then you conduct another test as it is ground up?

Cleaning the—my uncle was a butcher and, you know, we always cleaned the—I used to clean the grinding machines. If I slipped up and didn't clean the grinding machines just right, well, somebody could have—it could have been contaminated at that level.

Then you get to the next level is you make the hamburger patty. Some people touch them with human hands actually. There is contamination at that level. We need the space technology to look at it at that level. Then the next level is whether you put it on a grill or you charbroil it.

Mr. TORRICELLI. I know the process of making a hamburger.

Mr. MICA. I am saying there are so many processes that can we really create a fail-safe system?

Mr. TOWNS. Let me just say to the gentleman from Florida, that I agree with you that we cannot make it risk free, but I think we are talking about a lot of things here. We are talking about, first of all, 80 million illnesses that take place as a result of this. That is a lot of suffering and loss of money. We are talking about health care reform and we must work to prevent foodborne illness not just treat the victims. We are also talking about 9,000 deaths.

But the point is that I think what we need to try to do is at least reduce the risk. I think that is very, very important. This is the same country that can put a man or woman on the moon over the weekend. We should be able to inspect meat on earth. I yield back.

Mr. MICA. I agree with you, but I am just saying, you have to approach everything from a very logical standpoint. And let me say, I being the devil's advocate, of course, here——

Mr. TORRICELLI. That would be a fair description of it, yes, devil no doubt is in court.

Mr. MICA. We have had USDA here, and I can see that they have not performed their task well.

Mr. SCHIFF. Would the gentleman from Florida yield for one moment?

Mr. MICA. Just as soon as I am finished, if I may.

There are a lot of problems. There are problems with inspections. There are problems when for 5 or 6 continuous years they do not cite unsanitary producers. There are problems with their lack of response to some of the corrective measures that have been recommended by the Congress. So I am with you on that.

I just want to say that I like to look at things in a very practical, cost-effective sense, and maybe our efforts should be to improve what we are doing now. And I will work with you on that.

Mr. SCHIFF. Would the gentleman yield for one moment?

Mr. MICA. Yes.

Mr. SCHIFF. I just want to thank the gentleman for yielding a little bit of his time.

I just want to say that I think the issue, as I see it, is not this committee's evaluating right now each and every potential test or action that can be taken but evaluating who is making the decision about what tests and actions will be taken.

For example, in the last hearing, there was discussion about the possibility of labeling red meat warning consumers that they should cook this meat at a certain temperature in order to be sure to eradicate any dangerous bacteria.

Now that hasn't taken place yet. And that may be a debatable approach. But I can certainly see that that approach is inconsistent with an agency whose duty it is to try to promote the sale of that meat. You know, do you promote the sale of meat by warning people on the package that there could be a problem that they have to address?

So I think the—I just want to say I think the real issue comes back again to this conflict of interest, is the agency that is designed to increase the sale of meat in this country the right agency to make these decisions as to what kinds of processes might be added to the current system to improve the health situation?

I yield back to the gentleman from Florida.

Mr. MICA. Good point. Thank you, and Mr. Chairman——

Mr. TORRICELLI. Mr. Mica, could I respond—and I will conclude—to your points? No one is suggesting that there is any one answer or that this is easily accomplished. It is simply that there is a structural problem in the Federal Government that someone is not a sufficient advocate for the safety of our citizens in meat or poultry or there would have been a human cry a long time ago about this problem.

So we have a structural failure. And then we have allowed generations of Americans to come and go through this life without developing the technologies to assure that meat and poultry are safe.

You are quite correct. There is not a technology on the shelf that can be moved into the slaughterhouse today to assure that these bacteria do not exist. I do not accept that that is impossible. I am sure the technology can be developed that is better than sending some inspector in with their eyes open and their nose sniffing gayly in the wind. We can do better than that.

And finally, Mr. Mica, at a minimum, we know that higher temperatures and longer cooking will kill most of this bacteria. Maybe it won't save all 9,000, but it is going to save most, many. Certainly, at a minimum, we can impose the cost on the fast food industry that this food be cooked for a certain amount of time at a certain temperature that we know will kill the bacteria. That we can do.

Believe me, if you don't pay your change walking out of McDonald's, they detect it. They can at least have some little bell that goes off if some 18-year-old kid who is in a hurry, doesn't really

know how to cook a hamburger, takes it off before it is hot enough and kills your child. At a minimum we can ask that.

Mr. TOWNS. Let me say the gentleman's time has really expired.

Mr. Portman.

Mr. PORTMAN. Congressman, thank you for coming. I have no questions. Unfortunately, I missed your testimony. I will be reviewing it afterwards. I am very interested in the notion of restructuring the way we inspect both fish and poultry and meat and interested particularly in hearing from USDA and seeing what their reaction is to your suggestions. And thank you for being here this morning.

Mr. TORRICELLI. Thank you.

Mr. TOWNS. Congressman Payne.

Mr. PAYNE. Thank you, Mr. Chairman.

Let me say that it is a pleasant surprise to see my colleague from New Jersey here. I was unaware of that until I came in. I would not have been late had I known you were here. I certainly—and this is something that we certainly agree on. It is, though, important I think that you brought to the attention—and I am sorry that I also missed your testimony, but about the unfortunate situation with Katie O'Connell, and I appreciate you taking this interest, and we look forward to working with you from this committee in the future.

And, Mr. Chairman, I ask unanimous consent to have my opening statement included in the testimony.

Mr. TOWNS. Without objection.

[The prepared statement of Mr. Payne follows:]

Hearing--HRIR
Statement
Rep. Donald Payne
November 19, 1993

Good Morning. I would like to commend the Chairman for his leadership in calling this hearing today. I would like to extend my regards to the panel of witnesses who have agreed to provide us with their testimony.

Food safety is very important to our society and this issue is causing increasing concern.

On November 15, 1992, an outbreak of a potentially deadly and infectious strain of E. coli (EE -- CO LIE) that lasted through February 28, of this year caused more than 500 illnesses and 4 deaths in 4 Western states. This outbreak was linked to undercooked hamburgers from the fast food chain, Jack-in-the-Box.

USDA traced hamburgers to slaughtering and processing plants that distributed contaminated meats.

Since then, at least nine subsequent outbreaks have surfaced since that initial outbreak almost a year ago and the incidence of E. coli (EE -- CO LIE) infection is increasing.

Mr. Chairman, I was here two weeks ago when we heard the testimony of the victims of the E. coli outbreak. And particularly disturbing to me, is that the current system of meat and poultry inspection is not adequately designed to detect and control microbial pathogens in these foods.

I was further disturbed to hear that despite CDC estimates that attribute between 7,500 to over 20,000 deaths annually to E. coli poisoning, very little progress has been made to ensure that these incidents do not happen again.

I am sorry that the representation from the Department of Agriculture was unable to respond to some of the issues and perhaps shine some light on a very alarming trend.

Mr. Chairman, I would like to thank you again for bringing this very important issue to our attention and I look forward to hearing what our witnesses have say.

Mr. TOWNS. Let me thank our witness for his testimony and, as I indicated earlier, I look forward to working with you to bring about some real changes. So thank you, again.

Mr. TORRICELLI. Mr. Chairman, members of the committee, thank you.

Mr. TOWNS. Thank you. Now let me welcome Mr. Eugene Branstool, the Assistant Secretary of Marketing and Inspection Services at the U.S. Department of Agriculture.

Mr. Branstool, please introduce the person that is accompanying you today.

Mr. BRANSTOOL. Yes, Mr. Chairman, members of the committee.

Mr. TOWNS. Just a minute. What is her title?

Mr. BRANSTOOL. I have with me today Pat Jensen, who is the Deputy Assistant Secretary of Agriculture for Marketing and Inspection Services.

Mr. TOWNS. Right. It is the custom of this committee to swear in our witnesses so if you would just stand and raise your right hand.

[Witnesses sworn.]

Mr. TOWNS. Let the record show that the witnesses answered in the affirmative, and let me thank you very much, Mr. Branstool. But before I begin, I must express my disappointment and displeasure with your performance and that of your staff in cooperating with this subcommittee. Mr. Schiff sort of alluded to it earlier.

First, your written statement fails to address all the specific questions that we asked you to address in my letter to you of October 4. Second, you failed to provide a complete status report on all the Department's initiatives that we asked for in the letters of October 4, November 8 and the many phone calls that have been made and the meetings with this subcommittee staff.

Third, you failed to provide your written statement within the required amount of time. In fact, we received your testimony last night at 7 p.m. How do you expect the members of this subcommittee to take what you say seriously, if you do not provide ample time for them to study your statement? Mr. Assistant Secretary, if your process prevents you from complying with this subcommittee's request for testimony in a timely fashion, then I strongly suggest you go back to your Department and immediately change your process. We will not tolerate this. People are dying. This is a serious matter.

Now, kindly tell this subcommittee when it can expect to receive your written response to all the questions raised in my letter of October 4 and when it can expect a full and complete status report on all the Department's food safety initiatives as we requested in the letter of October 4, November 8, and the various meetings you have had with this subcommittee staff.

Let me just yield at this point in time to my ranking member. He indicated his frustration earlier. Do you have anything before we move forward?

Mr. SCHIFF. I think you said it all, Mr. Chairman. If you let me ask one question out of order.

Mr. TOWNS. Sure.

Mr. SCHIFF. Secretary Branstool, I note that the name of your particular position with the Department of Agriculture is Market-

ing and Inspection Services. What is the inspection itself—what is the marketing side of that?

Mr. BRANSTOOL. Representative Schiff, Mr. Chairman, I am the Assistant Secretary of Agriculture, Marketing and Inspection Services. There are five agencies within the area of my responsibility: the Federal Grain Inspection Service, the Packers and Stockyards Administration, the Agricultural Marketing Service, the Food Safety and Inspection Service, and the Animal and Plant Health Inspection Service.

Within the Agricultural Marketing Services there are several entities that do deal with the marketing of agricultural products—animals, cattle, hogs, soybeans, cotton, any number of——

Mr. SCHIFF. I am sorry to interrupt you, Mr. Secretary. The word marketing to me means promotion to sell. Is that what it means to you? Is that what we are talking about?

Mr. BRANSTOOL. Marketing can mean that, but it can also mean that there are honest weights at our grain elevators. There are honest weights and grades for producers and farmers at produce houses, grain terminals, grain elevators and also grading of quality factors on agricultural products.

Mr. SCHIFF. Does any responsibility fall under you, Mr. Secretary, that deals with the promotion of the sale of U.S. meat products in any way?

Mr. BRANSTOOL. Yes, it does. You know, there are any number of commodities where growers have agreed to have a check-off system to help market and promote and grade their products. So, yes, that is a responsibility within the Agricultural Marketing Service, but I would say to you that that is separate from the Food Safety and Inspection Service where we have the responsibility to grade meat and poultry.

Mr. SCHIFF. So it is all under—I am not picking on you personally, I assure you, Mr. Secretary, but institutionally it falls under one official, whether that is yourself right now or some other official in the future?

Mr. BRANSTOOL. Yes. As you know, there are 42 agencies within the Department of Agriculture. Five of them I have responsibility for.

Mr. SCHIFF. Well, obviously, the point I am getting at—and the point you heard. I am sure you heard the testimony, the past testimony, is just this question, are responsibilities mutually exclusive—and I know individually that might not seem to be the case, but I am getting reinforced in that idea here myself. And I stress again that is not addressing you personally. I want to make that very clear.

Mr. Chairman, I yield back, thank you.

Mr. PAYNE [presiding]. Thank you, and I think those points are certainly well taken. It seems to me there is almost a conflict when you have not only the responsibility of industry oversight, but also the responsibility of promoting, as it sounds, the whole marketing concept. I think we should do marketing, but I am not so sure it should be the same organization doing both. It seems at cross-purposes in my opinion but——

Mr. MICA. Mr. Chairman, if I might just make a comment out of order.

Mr. PAYNE. Yes.

Mr. MICA. I have, too, been asking information from the Department, and I am really stunned at their lack of response both to this subcommittee, our committee, and to individual members. And if this continues and we don't get the records, I will be prepared to offer a motion to subpoena or take whatever steps we need to get those records.

Really, I didn't come here to be stonewalled by bureaucrats, and I think we are getting stonewalled by them, both the committee, me individually.

I have had the same experience in another subcommittee on which I serve, and I am not going to put up with this. So I just offer that.

I am going to talk to Chairman Towns about that. If necessary, I am prepared—this side is prepared to assist you in whatever means necessary to acquire that information.

Mr. PAYNE. Well, thank you. And let me just say that, as a member of this committee for the past 5 years, we have used the subpoena, and we have no hesitation that if we find it necessary—that the administration has changed, but the problem remains the same. We were not reluctant to ask for subpoenas under an administration from the other side of the aisle. We will not be reluctant to ask for subpoenas to get information from an administration on this side of the aisle.

So I thank you for your comments.

Are there any other persons that want to speak out of order? We were attempting to get your testimony before we had to go to vote. The chairman will be back, and so at this time, Mr. Branstool, would you proceed?

Mr. BRANSTOOL. Yes. Thank you, Mr. Chairman, members of the committee.

Mr. SCHIFF. I don't mean to interrupt the Secretary, Mr. Chairman. But may I say, before the Secretary begins his testimony, might I suggest adjournment for the vote and come back, and we won't have to interrupt the witness?

Mr. PAYNE. All right. I will ask unanimous consent—all right. Then we will adjourn and wait until the chairman comes back.

[Recess taken.]

Mr. TOWNS [presiding]. The hearing will resume.

Mr. Branstool, please summarize your statement.

STATEMENT OF EUGENE BRANSTOOL, ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY PATRICIA JENSEN, DEPUTY ASSISTANT SECRETARY

Mr. BRANSTOOL. Mr. Chairman, members of the committee, I want to thank you for inviting me to appear before you today to discuss the meat and poultry inspection program at the U.S. Department of Agriculture. Today I am also joined by Deputy Assistant Secretary for Marketing and Inspection Services, Pat Jensen, who is from Minnesota.

Later in my testimony, I will refer to health and safety problems confronted in the State of Minnesota and the media attention that this attracted in a 1991 article. I mention this fact because Pat

adds both practical and knowledgeable resources to the USDA team effort to aggressively resolve and address these food safety issues.

Most importantly, I am here today to discuss the steps and actions that this administration has taken since January to literally and structurally improve the meat and poultry inspection system, thereby charting a course to ensure the safety of the U.S. meat and poultry supply.

I want to begin my testimony today by making very clear the priorities, the actions, the commitment and the dedication of Secretary Espy since he was sworn in just a little less than 10 months ago. I want to clarify any doubts that you may have regarding our resolve to ensure the health and safety of meat and poultry in this Nation.

Secretary Espy has exerted his leadership in the Food Safety and Inspection Service to achieve a higher standard and a greater level of commitment to food safety through stricter standards. He has mandated that all voices be heard, all opinions are to be considered and an open door policy is to be available to ensure greater public participation in the decisionmaking process.

As I mentioned previously, this administration has been in office not quite 10 months, but, believe me, we have done more for meat and poultry safety in 10 months than was accomplished in the past 10 years. Both Secretary Espy and I believe that if the previous administrations had taken the steps—the aggressive steps—that we have taken in the past 10 months, perhaps we would not have had to personally look into the faces of parents who lost their children. Yet, it is these losses that only furthers our resolve to fix the wrongs.

Mr. Chairman, if we had mandatory safe handling labels long ago, we may have prevented the deaths of several children. For example, the couple who lost their daughter because they undercooked hamburger meat said that if they would have known to cook it thoroughly, they would have done so. Had the USDA invested millions of dollars in pathogen research 10, 5 or even 2 years ago, we may have been able to prevent these deaths, found solutions to these contamination issues or discovered a method to eradicate or better identify pathogenic bacteria.

I cannot report to you today that this was done, and, frankly, I am not going to tell you that we have found the solutions, but I can tell you that this administration has taken the steps necessary to achieve the end results.

By no means do we have a silver bullet, and the committee should not be misled because there isn't a silver bullet at hand at this point. But we do have a multidirectional strategy to aggressively attack food safety issues from the farm to the table. Without such a multidirectional attack and plan, we may never be able to accomplish our objectives.

I am not here to point fingers today. I know that there were witnesses before this committee just last week who chose to point fingers and to lay blame. The fact of the matter is that pointing fingers doesn't produce results, and it is results that the health and welfare of the American public depend upon.

I am here to tell you that this administration recognizes this fact, and we have taken steps to address the problems.

So let me tell you what we have done in the past 10 months and then tell you of our future efforts as we continue to wage the war on pathogens with the end result of assuring the American public of the safety of our meat and poultry products.

Mr. Chairman, instead of going into a lengthy explanation of each action that we have taken, I want to simply list those steps.

Our efforts to initiate and accelerate change to improve the safety of the meat and poultry supply include directing several USDA agencies to join in the effort, including the Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, the Agricultural Marketing Service, the Agricultural Research Service, the Cooperative Extension Service and the Food Nutrition Service. All of these resources are being marshaled to improve the meat and poultry inspection program. As I note later in my testimony, the Department of Agriculture is also working closely with and coordinating our efforts with other agencies.

We have a proactive agenda to guide the meat and poultry inspection program which was left behind in the early 1990's and to guide it into the year 2000 and beyond. Part of this agenda includes the input from all interests and resources. We have met with whistleblowers, consumer groups, scientists, researchers, educators, veterinarians, farmers, ranchers, industry representatives, the medical community and the families of those affected by E. coli outbreaks. We recognize the need to make changes and the benefit that having input from all, including those who have felt left out in the past, will only help accomplish our objectives. It is taking this input and putting it to work that will ensure our ultimate success.

Earlier this year, the Food Safety and Inspection Service held six regional hearings on the two-track pathogen reduction strategy. The hearings were held all across the country from Seattle to Philadelphia. These hearings were helpful in the development of a strong, successful and aggressive pathogen reduction strategy as well as key to development of and updating our meat and poultry inspection program.

Specific changes under way at USDA to improve meat and poultry safety include: Hiring additional inspectors. The inspection force has been increased by 200. We are keeping hires up-to-date as inspectors leave the system. We are also providing better training to our inspectors to conduct microbiological monitoring.

We are enhancing veterinary coverage of identified slaughter plants which handle older and disabled animals.

We are reinforcing mandatory trimming of all fecal ingesta and milk contamination in slaughter operations.

We are moving into high gear a strategic pathogen reduction program that aims to prevent contamination from the farm to the table and to develop new inspection methods that are based on sound science. The two-track system includes moving the inspections toward a science based, risk-based system while at the same time improving the current system.

We are implementing the additional $8 million in the fiscal year 1994 appropriations to fund the pathogen reduction program as part of the administration's food safety initiative.

We have directed Food Safety and Inspection Service to conduct an all-out search for a rapid test for E. coli 0157:H7 as well as other pathogens. We have already published in the Federal Register a notice setting forth scientific criteria for test methods.

We are conducting comprehensive studies by both the Animal and Plant Health Inspection Service and the Food Safety and Inspection Service scientists. We are investigating the source and incidence of E. coli 0157:H7. We are also planning field studies for risk analysis, control and intervention strategies for E. coli. We are collecting baseline data on pathogen presence and monitoring trends. The Food Safety and Inspection Service and APHIS are working together with the Food and Drug Administration and the Centers for Disease Control to better develop investigation protocols.

We are conducting on-farm investigations. We are investigating current assumptions about sources and good preventive measures to develop models that may be used on the farm in the future.

We are researching the feasibility of development of a vaccine that may be used on the farm.

We are expanding our microbiological baseline program.

We are completing research on irradiation of fresh ground beef and beef trimmings.

We are encouraging the use of organic acid and other prevention systems to reduce pathogens on the surfaces of beef carcasses.

We are requiring mandatory labeling of meat and poultry with safe handling instructions. We must keep the consumer informed about the possible pathogen contamination of the current system that the current system is not able to detect. Up-to-date consumer information and advice is an important part of our responsibility to ensure safe food. The Secretary stands committed to that responsibility.

The safe handling instruction effort has been delayed, as you know, by a lawsuit. Despite this delay, we are moving forward with administrative action and intend to have the labels on not-ready-to-eat meat and poultry by early next year. Furthermore, we are aggressively campaigning for voluntary compliance and already these safe handling instruction labels are visible in the marketplace.

In addition, the Food and Nutrition Service has joined the Food Safety Inspection Service with a campaign to spread the word about safe cooking and handling of meat and poultry to recipients of USDA commodities. The Food Nutrition Service, for example, will be printing posters for homeless shelters and soup kitchens. The Food Safety and Inspection Service is preparing a video for training child care providers. We are also conducting information campaigns targeted at school lunch workers and restaurant employees.

We have directed Food Safety and Inspection Service managers at all levels to help spread the word about a new attitude at the Department of Agriculture. We want the USDA to have a new attitude about providing better service in all agencies, and Secretary

Espy is constantly pushing to have this new attitude expressed on the line in slaughterhouses and every other stage of meat and poultry processing.

We have directed the USDA to conduct a special review of plants throughout the country. Out of 90 plants reviewed, 52 plants had problems that were corrected. Some corrections required shutdowns; 12 plants were placed under Progressive Enforcement Action.

These unannounced reviews were conducted by a special team that Secretary Espy directed FSIS to undertake. This team is based in Lawrence, KS. It will conduct special reviews throughout the year and make quarterly reports to the Secretary. More recently, this special team finished reviewing 26 turkey plants, and the results of that review will be available in mid-December.

In addition to addressing concerns at individual plants, the turkey plant review also included interviewing 128 inspectors. USDA wants to hear suggestions and comments from those on the front lines about how we may improve the system.

We are preparing a Federal Register notice on the formation of a public roundtable to receive input from all interests regarding USDA's announcement on its intention to mandate a HACCP system—hazardous analysis critical control point system—to be implemented. This process is designed to gather vital information on the details and recommendations of implementing a mandatory HACCP system. This will assist USDA in presenting a solid proposal which is designed to provide a safer meat and poultry system.

We have directed FSIS to add a public health adviser. A public health emphasis at the Food Safety and Inspection Service is long overdue. In addition, we recently completed a video conference along with Health and Human Services to State and local public health authorities around the country to share information on food safety requirements.

We have implemented stricter rules and guidelines on cooked meat patties.

We have directed the Food Safety and Inspection Service to create a profile of plants, like the Cornhusker plant in Nebraska, that are likely to have problems. Once the profile is created, plants that fit that profile must be identified, and special reviews will be conducted.

We are preparing a legislative package that will increase our ability to trace back the source of pathogens and control their presence on meat and poultry products. As you know, this was one of the problems in the current system that made investigating the E. coli outbreak earlier this year in the Northwest more difficult.

And we are reorganizing the Food Safety and Inspection Service staff to better implement the changes.

Many of these changes are basic and long overdue. These are just a few of the changes underway.

Mr. Chairman, I would like to explain part of the reason that this administration is so committed to correcting and improving the safety of our meat and poultry supply. We are willing to look at the weaknesses and target our resources to strengthen them.

We will improve the system based on what we learn in the process and what we can learn from the past. For example, in 1991,

a Pulitzer prize winning series written by the Kansas City Star brought to attention what change is needed at the Department of Agriculture and, in particular, the Food Safety and Inspection Service.

Earlier in my testimony, I referenced the health and safety problems confronted in the State of Minnesota which were included in this article. In October 1988, Minnesota had an outbreak of E. coli 0157:H7 affecting school children in the Twin Cities area. The outbreak was caused by consumption of heat processed meat patties that should have been pathogen free when they were distributed from a manufacturing plant. The Minnesota Departments of Health and Agriculture worked cooperatively to pinpoint the cause of the outbreak and to inform the public. Minnesota has developed a strong response mechanism to act quickly and aggressively to such outbreaks.

That response includes interagency cooperation, media advisories for public information, increased sampling and testing, improved state laboratory ability, cooperation with universities for research, communication with legislative committees and dialog with Federal agencies. It is this kind of program we are developing on the Federal level. Deputy Assistant Secretary Jensen's experience was directly involved in the development of this program. These type of ideas and resources will be essential to accomplishing our objectives.

In a Kansas City Star editorial that ran in conjunction with this 1991 series, it was stated that in terms of food safety and inspection at USDA, "Oversight responsibilities are not taken seriously; at one point the head of the recall department said there were no bad meat packers. People are misled when they think the USDA stamp of approval as meaning that everything is OK." And later in the editorial it stated, "The USDA needs an overhaul."

Well, based on my testimony today, I am here to report to you that the overhaul has begun and will continue. The oversight responsibilities are now taken seriously. Reforms have been mandated. We know that there are bad meat packing plants because we have gone in and shut the plants down and will continue to shut down those type of plants.

We have admitted that the USDA stamp of approval isn't the last word. This is evidenced by our mandatory safe handling label which informs the public to properly care and refrigerate and cook meat and poultry products. And, on this label, it clearly states that there may be some food products that may contain bacteria that can cause serious illness.

So we agree, USDA needs an overhaul, and it is getting an overhaul as evidenced by the points listed above. But we are going to do more. For example, we have held meetings with whistleblowers to legitimately know and hear their concerns as well as we have worked to ensure that their recommendations are incorporated into our program. Secretary Espy has opened the previously closed door to hear the interests and concerns of all. It is through these ideas, whether they be from elected officials, farmers, consumers, scientists, industry and others that we will be able to change and overhaul the USDA.

Finally, I want to say, Mr. Chairman, that Secretary Espy has demonstrated by the actions that he has taken and by his future plans for the Department that we can do the job and that we will do the job to ensure that the USDA label means what it says, that the product is healthy and safe.

Mr. Chairman, this is what we have done, and this is what we are going to do. We will continue to work toward these goals, but to accomplish these objectives, we need your help and the help of Congress to achieve them. The Secretary has continually stated that improving the meat and poultry inspection system is a top priority at USDA. This is part of his personal agenda. And after knowing Secretary Espy for just a short amount of time that I have been here, I know that he means business.

Mr. Chairman and members of the committee, I have with me today our senior people in the Food Safety and Inspection Service: Dr. Ann Marie McNamara, who is the Director of Microbiology at the Food Safety and Inspection Service; Pat Stolfa, who is project manager for Pathogen Reduction and Acting Deputy Administrator for Science; Dr. Russell Cross, the Administrator of the Food Safety and Inspection Service; Dr. Don Luchsinger, Associate Deputy Administrator, Veterinary Services from the Animal and Plant Health Inspection Service; Dr. Craig Reed, Deputy Administrator, Inspection Operations; and Dr. Jill Hollingsworth, Assistant to the Administrator.

We stand ready to receive and do our best to answer your questions. I believe that our staff people here can be very helpful in help understanding the technology and the science that we struggle with to deal with pathogens in our food supply.

Mr. TOWNS. Thank you very much for your testimony.

[The prepared statement of Mr. Branstool follows:]

STATEMENT OF
MR. EUGENE BRANSTOOL
ASSISTANT SECRETARY FOR MARKETING AND INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE
BEFORE THE
HOUSE COMMITTEE ON GOVERNMENT OPERATIONS
SUBCOMMITTEE ON HUMAN RESOURCES
AND INTERGOVERNMENTAL RELATIONS
U.S. HOUSE OF REPRESENTATIVES

November 19, 1993

Mr. Chairman and members of the Committee, I want to thank you for inviting me to appear before you today to discuss the meat and poultry inspection program at the U.S. Department of Agriculture (USDA). Today, I am also joined by Deputy Assistant Secretary for Marketing and Inspection Services Pat Jensen, who is from Minnesota. Later in my testimony, I will refer to health and safety problems confronted in the State of Minnesota and the media attention that this attracted in a 1991 article. I mention this fact because Pat adds both practical and knowledgeable resources to the USDA team effort to aggressively resolve and address these food safety issues.

Most importantly, I am here today to discuss the steps and actions that this Administration has taken since January to literally and structurally improve the meat and poultry inspection system, thereby charting a course to ensure the safety of U.S. meat and poultry products.

I want to begin my testimony today by making very clear the priorities, the actions, the commitment and the dedication of Secretary Espy since he was sworn in just a little less than 10 months ago. I want to clarify any doubts that you may have regarding our resolve to ensure the health and safety of meat and poultry in this nation. Secretary Espy has exerted his leadership of the Food Safety and Inspection Service to

achieve a higher standard and greater level of commitment to food safety through stricter standards. He has mandated that all voices are to be heard, all opinions are to be considered, and an open door policy is to be available to ensure greater public participation in the decision making process.

As I mentioned previously, this Administration has been in office not quite ten months, but believe me we have done more for meat and poultry safety in ten months than was accomplished in the past ten years. Both Secretary Espy and I believe that if previous Administrations had taken the steps --- the aggressive steps -- that we have taken in the past ten months, perhaps, we would not have had to personally look into the faces of parents who lost their children. Yet, it is these losses that only furthers our resolve to fix the wrongs.

Mr. Chairman, if we had mandatory safe handling labels long ago, we may have prevented the deaths of several children. For example, the couple who lost their daughter because they undercooked hamburger meat said that if they would have known to cook it thoroughly, they would have done so. Had USDA invested millions of dollars in pathogen research -- 10, 5 or even 2 years ago we may have been able to prevent these deaths, found solutions to these contamination issues or discovered a method to eradicate or better identify pathogens. I cannot report to you today that this was done and frankly I am not going to tell you that we have found the solutions, but I can tell you that this Administration has taken the steps necessary to achieve these end results.

By no means do we have a "silver bullet" and the Committee should not be misled -- there isn't a "silver bullet" at hand at this point. But, we do have a multi-prong strategy to aggressively attack food safety issues from the farm to the table. Without

such a multi-prong attack and plan, we may never be able to accomplish our objectives.

I am not here to point fingers today. I know that there were witnesses before this Committee just last week who chose to point fingers and lay blame. The fact of the matter is that pointing fingers doesn't produce results -- and it is results that the health and welfare of the American public depend upon. But I want to make it clear, there is blame to lay at USDA, but I am here to tell you that this Administration recognizes this fact and we have taken steps to address the problems.

So let me tell you what we have done in the past ten months and then tell you of our future efforts as we continue to wage the war on pathogens with the end result of assuring the American public of the safety of our meat and poultry products.

Mr. Chairman, instead of going into a lengthy explanation of each action that we have taken, I want to simply list those steps:

Our efforts to initiate and accelerate change to improve the safety of the meat and poultry supply include directing several USDA agencies to join in the effort including the Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, the Agricultural Marketing Service, the Agricultural Research Service, the Cooperative Extension Service and the Food Nutrition Service. All of these resources are being marshalled to improve the meat and poultry inspection program. As I note later in my testimony, USDA is also working closely with and coordinating our efforts with other agencies.

We have a proactive agenda to guide the meat and poultry inspection program which was left behind in the early 1900's -- into the Year 2000 and beyond. Part of this

agenda includes the input from ALL interests and resources. We have met with whistle-blowers, consumer groups, scientists, researchers, educators, veterinarians, producers, industry representatives and the families of those affected by E.coli outbreaks to name a few. We recognize the need to make changes and the benefit that having input from ALL, including those who have felt left out in the past, will only help accomplish our objectives. It is taking this input and putting it to work that will ensure our ultimate success.

Earlier this year, FSIS held six regional public hearings on the two-track pathogen reduction strategy. The hearings were held all across the country from Seattle to Philadelphia. These hearings were helpful in the development of a strong, successful and aggressive pathogen reduction strategy as well as key to development of and updating our meat and poultry inspection program.

Specific changes underway at USDA to improve meat and poultry safety include:

- Hiring additional inspectors. The inspection force has been increased by 200. We are keeping hires up-to-date as inspectors leave the system. We are also providing better training to our inspectors to conduct micro-biological monitoring.
- Enhancing veterinary coverage of identified slaughter plants which handle older and disabled animals.
- Reinforcing mandatory trimming of all fecal and milk contamination in slaughter operations.
- Moving into high gear a strategic pathogen reduction program that aims to prevent contamination from the farm to the table and to develop new inspection

methods based on sound science. The two-track system includes moving the inspections toward a science-based, risk based system while at the same time improving the current system.

• Implementing the additional $8 million in the FY 1994 appropriations to fund the pathogen reduction program as part of the Administration's food safety initiative.

• Directing FSIS to conduct an all-out search for a rapid-test for E.coli 0157:H7 and other pathogens. We have already published in the Federal Register a notice setting forth criteria for test methods.

• Conducting comprehensive studies by both APHIS and FSIS scientists. We are investigating the source and incidence of E.coli 0157:H7. We are also planning field studies for risk analysis, control and intervention strategies for E.coli. We are collecting baseline data on pathogen presence and monitoring trends. FSIS and APHIS are working together with the FDA and CDC to develop better investigation protocols.

• Conducting on-farm investigations. We are investigating current assumptions about sources and good preventive measures to develop models that can be used o n the farm in the future.

• Researching the feasibility of development of a vaccine to be used on the farm.

• Expanding our microbiological baseline program.

• Completing research on irradiation for fresh ground beef and beef trimmings.

• Encouraging the use of organic acid and other prevention systems to reduce

pathogens on surfaces of beef carcasses.

• Requiring mandatory labelling of meat and poultry with safe handling instructions. We must keep the consumer informed about the possible pathogen contamination that the current system is not able to detect. Up-to-date consumer information and advice is an important part of our responsibility to ensure safe food. The Secretary stands committed to that responsibility.

The safe handling instruction effort has been delayed by a lawsuit. Despite this delay, we are moving forward with administrative action and intend to have the labels on not-ready-to-eat meat and poultry by early next year. Furthermore, we are aggressively campaigning for voluntary compliance and already these safe handling instruction labels are visible in the marketplace. In addition, the Food and Nutrition Service (FNS) has joined FSIS with a campaign to spread the word about safe cooking and handling of meat and poultry to recipients of USDA commodities. The FNS, for example, will be printing posters for homeless shelters and soup kitchens. The FSIS is preparing a video for training child care providers. We are also conducting information campaigns targeting school lunch workers and restaurant employees.

• Directing FSIS managers at all levels to help spread the word about a new attitude at USDA. We want USDA to have a new attitude about providing better service in all agencies -- and Secretary Espy is constantly pushing to have this new attitude expressed on the line in slaughterhouses and every other stage of processing and dressing.

• Directing USDA to conduct a special review of plants throughout the country. Out of the 90 plants reviewed, 52 plants had problems that were corrected. Some corrections required shutdowns. 12 plants were placed under Progressive Enforcement Action (PEA).

These unannounced reviews were conducted by a special team that Secretary Espy directed FSIS to create. This team, based in Lawrence, Kansas, will conduct special reviews throughout the year and make quarterly reports to the Secretary. More recently, this special team finished reviewing 26 turkey plants and the results of that review will be available in mid December.

In addition to addressing conditions at individual plants, the turkey plant review also included interviewing 128 inspectors. USDA wants to hear suggestions and comments from those on the front lines about how to improve the system.

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• Directing FSIS to add a public health advisor. A public health emphasis at FSIS is long overdue. In addition, we recently completed a videoconference along with HHS to state and local public health authorities around the country to share

information on food safety requirements.

• Implementing stricter rules and guidelines for cooked meat patties.

• Directing FSIS to create a profile of plants, like the Cornhusker plant in Nebraska, that are likely to have problems. Once the profile is created -- plants that fit that profile must be identified and special reviews will be conducted.

• Preparing a legislative package that will increase our ability to trace-back the source of pathogens and control their presence on meat and poultry products. As you know, that was one of the problems in the current system that made investigating the E.coli outbreak earlier this year in the Northwest more difficult. And,

• Reorganizing FSIS staff to better implement the changes.

Many of these changes are basic and long overdue. These are just a few of the changes underway.

Mr. Chairman, I would like to explain part of the reason that this Administration is so committed to correcting and improving the safety of our meat and poultry supply. We are willing to openly look at the weaknesses and target our resources to strengthen them.

We will improve the system based on what we learn in the process and what we can learn from the past. For example, a 1991 Pulitzer prize winning series written by the Kansas City Star has brought to attention what change is needed at U.S. Department of Agriculture and in particular, the Food Safety and Inspection Service.

Earlier in my testimony, I referenced the health and safety problems confronted in

the State of Minnesota which were included in this article. In October 1988, Minnesota had an outbreak of E. Coli 0157:H7 affecting school children in the Twin Cities area. The outbreak was caused by consumption of heat processed meat patties that should have been pathogen free when they were distributed from the manufacturing plant. The Minnesota Departments of Health and Agriculture worked cooperatively to pinpoint the cause of the outbreak and to inform the public. Minnesota has developed a strong response mechanism to act quickly and aggressively to such outbreaks.

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In a Kansas City Star editorial that ran in conjunction with this 1991 series, it was stated that in terms of food safety and inspection at USDA "Oversight responsibilities are not taken seriously; at one point the head of the [FSIS] recall department said there were no bad meat packers. People are misled when they think of the USDA stamp of approval as meaning that everything is OK." And later in the editorial, it stated "The USDA needs an overhaul."

Well, based on my testimony today, I am here to report to you that the overhaul has begun and will continue. The oversight responsibilities are now taken quite

seriously, reforms have been mandated. We know that there are bad meat packing plants, because we have gone in and shut down the plants and continue to shut down plants. We have admitted that the USDA stamp of approval isn't the last word. This is evidenced by our mandatory safe handling label --- which states that some food products may contain bacteria that could cause illness.

So, we agree -- USDA needs an overhaul and it is getting an overhaul as evidenced by the points listed above. But, we are going to do more. For example, we have held meetings with whistle blowers to legitimately know and hear their concerns as well as worked to ensure that their recommendations are incorporated into our program plans. Secretary Espy has opened the previously closed door to hear the interests and concerns of ALL. It is through these ideas whether they be from elected officials, farmers, consumers, scientists, industry, and others that we will be able to change and overhaul USDA.

Finally, I want to state that Secretary Espy has demonstrated by the actions that he has taken, and by his future plans for the Department, that we can do the job and that we will do the job to ensure that the USDA label means what it says -- that the product is healthy and safe.

Mr. Chairman, this is what we have done; this is what we are going to do. We will continue to work towards these goals, but to accomplish these objectives, we need your help and the help of Congress to achieve them. The Secretary has continually stated that improving the meat and poultry inspection system is a top priority at USDA. This is part of his personal agenda. And after knowing Secretary Espy for even just a short amount of time -- I know he means business.

Mr. TOWNS. Let me indicate that if you have staff members that provide testimony, they will have to be sworn in. So I want to alert you to that.

Mr. Branstool, when can this subcommittee expect complete answers to the questions in my letter of October 4?

Mr. BRANSTOOL. Mr. Chairman, the information that you still need and have not yet received, our staff is willing to meet with your staff immediately after this hearing, and I believe we can have it very quickly.

Mr. TOWNS. I sure hope so, because there have been several meetings and phone calls and with no results. So I just wanted to——

Mr. BRANSTOOL. I understand that some information has been given, but also I recognize more information is necessary. We will provide that.

Mr. TOWNS. When can we expect a complete status report on all of USDA's food safety initiatives addressed in both my letter of October 4 and my letter of November 8, specifically a list of all results to date and projected timeframes for completion?

Mr. BRANSTOOL. I have a list of the pathogen program initiatives that are in abbreviated form, the description of the initiative and also the status. The additional information, I have that available now, additional information that you may need. We will gladly provide that, and I believe, as far as I know, most of the things can be made available probably by the close of business on Monday.

Mr. TOWNS. We look forward to that, and we will leave the record open to receive it.

[The information can be found in appendix 3.]

Mr. BRANSTOOL. And I will say that our staff will meet with your respective staff people to know exactly what you yet need, and we will do everything we can to make it available.

Mr. TOWNS. Thank you.

Since 1985, three NAS reports have all concluded that USDA's current inspection approach to meat and poultry is inadequate because it cannot protect against microbial agents that cause disease in humans. In testimony before the Senate subcommittee earlier this year, Secretary Espy agreed with this. Do you agree with that?

Mr. BRANSTOOL. Yes. I agree that under our present inspection system, we can only visually examine—and as we are required by law to inspect every bird and every carcass, that has to be done visually. Now the difficulty is that, while there are pathogenic tests available, they take extended periods of time so——

Mr. TOWNS. I think that is a yes or a no, isn't it? That answer would be a yes or a no.

Mr. BRANSTOOL. Yes. I would say, yes. I agree with that, but I did want to qualify it, but that is fine.

Mr. TOWNS. Here is a chicken that I purchased at my local grocery store. It carries a stamp on the front that reads, USDA inspected for wholesomeness. Now, Mr. Branstool, because this bird passed Federal inspection, can I as a consumer assume that it is free of deadly bacteria? Yes or no.

Mr. BRANSTOOL. No.

Mr. TOWNS. Given all the progress you claim the Department has made in the last 10 months, can your inspectors, right now, today

as we speak, detect and prevent deadly bacteria on this chicken or any other animal product?

Mr. BRANSTOOL. Do you want that a yes or no answer? I would like to have a chance to qualify that.

Mr. TOWNS. I think it is a yes or no.

Mr. BRANSTOOL. No. No one in good faith can guarantee that there are no bacteria present in any organic substance.

Mr. TOWNS. Your testimony refers to the successful pathogen reduction program as one of the key things you have accomplished in the last 10 months. Well, tell us, Mr. Branstool, exactly how much has your program reduced the pathogens on my chicken that I purchased in my local grocery store? I need to know because we are a week away from a major turkey day known as Thanksgiving, and a lot of birds will be consumed. I need to know.

Mr. BRANSTOOL. Yes. The thing that we can say is that we believe we have improved the cleanliness in our plants. We have improved the vigilance of our inspection. But we have to also recognize bacteria cannot be seen with the naked eye. We know that—and part of the initiatives that I outlined to you are steps taken so that we can be able to get a better reading on the level of bacteria, harmful bacteria.

We have put in place what we call a zero tolerance program of no fecal or ingesta contamination or milk contamination from dairy cows that are slaughtered and processed. But, having said that nature does as nature does. There are bacteria present, and that is why it is my view that, you know, inspection will be very much a part of this. The research that comes forth will be part of this. But also every one of us has a responsibility.

And even if meat is properly inspected—and everything. Even if there is no contamination from the farm through the slaughter and processing process. Even then there still is responsibility from transportation to retailing and, yes, in the home to all of us to properly handle and cook and refrigerate.

Mr. TOWNS. But the whole zero tolerance procedure that you described does not apply to chickens, right? Does it apply to chickens as well, the zero tolerance policy?

Mr. BRANSTOOL. You mean the proper care and handling of?

Mr. TOWNS. Yes.

Mr. BRANSTOOL. Yes, sir.

Mr. TOWNS. Zero tolerance applies to chicken? It is my understanding it does not apply.

Mr. BRANSTOOL. I will call our Chief of Inspection Services to give us the technical detail of that if that would be all right——

Mr. TOWNS. Yes, because I want to know when you will be able to reduce the pathogens on my chicken. That is what I would like to know. Can he answer that?

Mr. BRANSTOOL. I don't think anyone can say—until the science presents itself. You know, irradiation has been approved by the Food and Drug Administration. Scientists give that high marks as a method to reduce pathogens in our poultry products, you know, but there is some concern. Consumer groups oppose that, and there is some reluctance on the part of industry to put that in place even though it has been approved. But I want to be real careful that——

Mr. TOWNS. I see, because a whole lot of progress hasn't been made in the last 10 months. Really, when you sit down and analyze it, not a lot of progress has been made.

Mr. BRANSTOOL. Well, no one can guarantee, and maybe we will never be able to guarantee that this product is totally safe. There are responsibilities that we all have from the farm to the table. As science presents itself, the worst thing we can do is to give incorrect information, and if the science is not there to allow us to make that pledge that you seek, you know, we can't do it yet. We have put in place initiatives that we hope will nurture the scientific community to present the things that we need so that we can improve not only our inspection system but also the general safety of our food supply.

Mr. TOWNS. Help educate us, Mr. Branstool. On the front of this chicken it has government inspected. What does that really mean?

Mr. BRANSTOOL. It means that the birds and livestock that come to a meat processing plant or a poultry processing plant, that our inspectors have inspected the processes that are required to make it edible—to make meat presentable for sale to the public. It deals with cleanliness in plants. It deals with certain procedures that have to be followed. They inspect for disease in poultry and animals that could cause disease, animalborne diseases that could also cause disease to humans. So that is our process.

But, you know, again, there is no way that in plants we can do a test. Much hope is held out for a quick test that would indicate that, yes, it has got E. coli or it is clear. The science has not yet come that far yet.

I would say to you on this subject, I have toured poultry plants. I have been in swine processing plants and beef plants. There is a plant in Grand Island, NE. Last August when I was there, they have done 17,000 samples seeking the presence of E. coli 1057:H7. Not one of those samples has indicated that it was positive, and this is a company that supplies meat, ground beef to major fast food chains, and the fast food industry, obviously, is greatly concerned, as you are, as I am, and so they are trying to do this testing.

E. coli is a very elusive organism. Much needs to be understood about it, and I do have the Director of our Microbiology present that I believe can enlighten this committee.

Mr. TOWNS. I am going to yield at this time to Mr. Mica. But as I look at this sign, it says inspected by the government. When people see this, you know, they feel that a real inspection has gone on, and there is a degree of safety here. It seems to me it needs to say inspected by the government, eat at your own risk.

Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman. I am trying to look through your testimony here. Can you all tell me when people eat the most turkeys in the United States?

Mr. BRANSTOOL. Well, I am sure our National Agricultural Statistics Service could give you chapter and verse, but, obviously——

Mr. MICA. Around Thanksgiving?

Mr. BRANSTOOL. Thanksgiving, Christmas, New Year's, of course.

Mr. MICA. I saw in your testimony that you said we have a responsibility to inform the public, and I thought I heard you testify

that we have inspected 26 turkey plants, and you plan to announce the results—the findings in mid-December?

Mr. BRANSTOOL. Yes. What I said there was that one of our initiatives is to send in review teams to inspect our turkey processing plants. I understand there are 2,000 pages of data gathered, and we are compiling that, and it will be available by mid-December. It had nothing to do with the season of the year or anything.

Mr. MICA. I know. But I mean, wouldn't just common sense indicate that you should have a review of the turkey plants prior to Thanksgiving when people consume most of that commodity?

Mr. BRANSTOOL. Yes. Well, just the timeframe that it worked——

Mr. MICA. Well this whole process, some of it, it seems to be a common sense approach. If you are going to put out warnings or the results of what your inspections have, wouldn't it be wise to do it prior to that type of season when you would have the highest consumption?

Another thing I notice that in your plans here—and we just got some of this information—you have education of the public as one of the elements, and you basically say that some of that is—that responsibility is completed.

I noticed also in your funding—let me see. It says intensify consumer awareness campaign. You budgeted zero under your pathogen reduction. Is that correct? This is for the plans to spend the additional funds in 1994 that the—that the Congress has appropriated.

Mr. BRANSTOOL. And, sir, you are talking about money to inform the public, is that——

Mr. MICA. Well, it says consumer awareness. It is on the schedule, pathogen reduction that we have here from you all, and you all divided up the funds to come to the $8 million, and it is zero under intensify consumer awareness campaign.

Mr. BRANSTOOL. Right. I understand that. I might have Dr. Cross, the Administrator, answer. That is of a technical nature. I think he can shed light.

Mr. MICA. Well, again, my point is that some of this seems to be a common sense approach that there is education of the public, there is education of food handlers, and that seems like a very important element, and some of it, I am not sure if your planning addresses it. Then, again, you just provided the committee with some of this background information.

One of your objectives is to tighten enforcement through unannounced reviews of slaughter plants as one of your objectives. I thought USDA law requires that there is an on-line inspector in slaughter plants.

Mr. BRANSTOOL. Yes, that is right. By law, as I mentioned and as you clearly state, that every bird, every carcass has to be inspected, but this is a backup to make sure that we can improve upon that ongoing inspection that takes place. And so we have teams that we send in unannounced to do these reviews.

Mr. MICA. Another point that I have—and these are questions—I see your initiatives and pathogen reduction program initiatives. On page 4, the system item, test raw ground beef. It says test raw ground beef patties for total E. coli count, and it says, initiated testing began, I guess, this month. Is that correct? And then we

had you all certify—or announce in that May study that you don't—I guess you don't have a rapid test still in place. Is that correct?

Mr. BRANSTOOL. That is correct.

Mr. MICA. So this is an existing test just to detect the E. coli bacteria?

Mr. BRANSTOOL. Yes. One of the difficulties with having a quick test—and again I would encourage you to get some scientific data from our microbiologist—but one of the difficulties with a quick test for E. coli, it is a rare, emerging pathogen. It is very virulent. It is very rare. And so in order to confirm that it is, in fact, E. coli 1057:H7, it has to be multiplied. They call it enrichment. That takes time, and there is no way in slaughter animals that have to be chilled quickly after slaughter that that can proceed with the science that we have now, and that is why the initiative where we are asking the scientific community to help us find the right methods to——

Mr. MICA. Right, and I would like to say that I notice you also have a fair amount of resources dedicated to developing tests and research which looks adequate, but I have to get back, and I don't want to take too much of the subcommittee's time here, on the education portion.

Again, on your initiatives, you list educate food handlers. You have completed and will be ongoing. Under educate fast food restaurant employees, you have as your initiative "completed." I think you need to go back and add "ongoing." Because——

Mr. BRANSTOOL. Surely.

Mr. MICA. Because, again, part of this, it seems to be common sense, common sense that you announce some time before Thanksgiving what your risks are to the general public in consumption of turkeys. If you got a bad plant out there, bad product, the consumer should know and you might save a lot of lives or upset Thanksgiving consumers, veal consumers, but some of it makes—you know, boils down to common sense. And then using your resources also in the proper fashion as far as educating fast food handlers, fast food restaurant employees, people who are in the preparation. And I think that—I am not an expert on this—but a lot of these people would not have gotten sick or died through just simple education.

One other thing I noticed is you had no funds—you testified that you support the—and maybe I am wrong on this—the labeling. You support the labeling, and then you have nothing under here for a labeling program under your proposal.

So, again, I am just trying—you know, I am that little remote voice in the bowels of the Congress asking for a common sense approach that the Department educate consumers that we do this in a fashion that doesn't cost an exorbitant amount of money and has good results at the end.

Mr. BRANSTOOL. Mr. Chairman, Congressman Mica, at the USDA, we are in the food business. Various agencies are helping on this. For instance, the Extension Service, through their newsletters, their weekly columns, county extension agents and home economists are getting the word out.

The one good science that we can tell people now with a high degree of assuredness is that the proper handling and cooking of our products—and we found that this summer—even after the outbreak of E. coli in the Northwest—there were sporadic outbreaks of E. coli—some of which connected to beef, a significant amount connected to other sources of contamination. But it is an ongoing thing, and that is why the label.

You know, we did have a setback in the court system, and that is why we are pursuing this through rulemaking, and I am glad to say to you that, you know, much of industry has already—even though by law they are not required, they have taken the initiative to put the label that this product may contain bacteria that could be harmful.

And so this is the first thing that we can do that the science does indicate is right, and that is why the other initiatives to bring forth these other areas, some of which are unknown now—as I said in my testimony, there is no silver bullet, but we are seeking that, and I believe the scientific community will be able to come forward.

Mr. MICA. I thank the chairman and yield back.

Mr. TOWNS. Thank you very much, Congressman Mica.

I now yield to Congressman Barrett.

Mr. BARRETT. Thank you, Mr. Chairman.

First, if I could ask unanimous consent to submit a statement for the record.

Mr. TOWNS. Without objection, so ordered.

Mr. BARRETT. Mr. Branstool, I am a new Member of Congress, a new member of the committee. Maybe you can help me. My understanding is that your agency is responsible both for promoting agriculture and food safety, is that right?

Mr. BRANSTOOL. Yes. As I mentioned earlier, I have five agencies that I am responsible for: The Federal Grain Inspection Service, the Packer and Stockyards Administration, the Agricultural Marketing Service, the Animal and Plant Health Service and the Food Safety and Inspection Service.

The Food Safety and Inspection Service deals only with the requirement that we inspect every bird and every carcass by law.

In the Agricultural Marketing Service, there are any number of activities that go on there, including the development of milk marketing orders, also the setting of grades and standards for fruits and vegetables as to size, color——

Mr. BARRETT. How is your budget broken down—roughly?

Mr. BRANSTOOL. In marketing?

Mr. BARRETT. Marketing versus food safety.

Mr. BRANSTOOL. I don't know that I can get that information, but let me say that, in most of the marketing programs, there is a check-off that pork producers have or cattle feeders have, cotton growers, et cetera. There is a check-off of their product, whether it be per bushel, per bale, per animal, per head, whatever.

The USDA—like the pork producers, for instance, you know, they have their own promotion program, but by law we have to oversee that to see that the money is accounted for and spent wisely and so forth.

Mr. BARRETT. My concern here—and maybe this applies very well here—is whether we have a situation here where the fox is

guarding the chicken coop. Because on the one hand you are trying to promote a product and on the other hand you are responsible for checking the safety. My concern is that one may take precedence over the other.

And, frankly, I was surprised—I learned something this morning because when I looked at the chicken and when the chairman was talking about it, as a consumer, picking up this chicken, inspected for wholesomeness by U.S. Department of Agriculture, I assumed that that meant this was safe, and what I am hearing this morning is that that is not the case. Am I correct?

Mr. BRANSTOOL. In the first part of your question you asked about how can you market a product, assist in the marketing of a product and then also be responsible for inspection. I can only speak for the 7 months that I have been here since I left my farm in Ohio——

Mr. BARRETT. I understand that. I am more interested in trying to find the right thing to do than painting you in a bad situation.

Mr. BRANSTOOL. The one thing I can say, and I am under oath now, and I will say it. I have never seen the first case since I have been there where there was ever even communication between the marketing folks and the inspection service people. And if that would come up, I will pledge to you what I know Secretary Espy feels real strong about: food safety comes first over marketing. And I will say this, and I have even sensed this from the people in the food production business: the best thing they have got going for them is confidence in their product. Without consumer confidence, they are in economic jeopardy, and I have sensed from industry and the pork producers and the cattle and the poultry industry, you know, when they have their labels on, they want to be able to have a safe product.

But I will say to you again that there would never be a case where we would have to say, well, this will affect sales or this will——

Mr. TOWNS. Will the gentleman yield 1 second?

Mr. BARRETT. Yes, Mr. Chairman.

Mr. TOWNS. You know, I think the gentleman's point is well taken. You know, you said there is marketing and inspection. Why shouldn't it be inspection and marketing? Why shouldn't it be the other way around? I think the gentleman has a good point.

Mr. BRANSTOOL. The only answer I can give, and maybe someone can help me, but I think, you know, some of the law sets forth what responsibilities USDA has. Now—but I don't know—I can't speak as to why it isn't named in that fashion. I would have no institutional memory that would give me an answer to that, unless the law requires that there will be like a Food Safety and Inspection Service which is located in USDA. You know, I know the law says that.

Now, the realm of the different agencies under one head, you know, however that has evolved over the years, I guess you may know more about that than I would.

Mr. TOWNS. One would think, if the gentleman will yield, one would think that inspection is sort of secondary just from general observation and listening to the comments. I yield back.

Mr. BARRETT. If I may, I look at this seal and to me it is a Good Housekeeping seal of approval, and it would make me more likely to buy this product. But you are saying that this does not ensure safety. What does this seal say to me again, please?

Mr. BRANSTOOL. That seal to me indicates that that bird has been processed in a plant that has been inspected by an USDA inspector, in a plant that has met the requirements as to equipment and cleanliness and so forth. That is what the seal says.

It does not say—and that is why we are promoting strenuously the label that says, you know, while this may be slaughtered under conditions that meet the requirements, it does not say, and I don't know anybody that can say that any organic product that has been—that has been slaughtered, that all along the way that there has to be vigilance on bacteria.

Mr. BARRETT. But I look at the——

Mr. BRANSTOOL. And so no one is indicating do anything you want with this product because it is safe. Nobody can say that or should.

Mr. BARRETT. I have the dictionary definition of wholesome and that is the adjective that you use there. Synonyms are healthful and healthy. So you are saying it——

Mr. BRANSTOOL. I am saying if the product is properly handled and cared for——

Mr. BARRETT. I am sorry. You said that no one can say this is healthy, but you are saying it is wholesome. And if you look at the dictionary definitions of wholesome, in essence, that is saying it is healthy. So on the one hand you are saying no one can say this is healthy, but USDA is saying it.

Mr. BRANSTOOL. No one can say that it is pathogen free and probably will never be able to say that up to the point of consumption.

Mr. BARRETT. But you are saying it. You are saying it on the label, aren't you?

Mr. BRANSTOOL. Maybe label identification needs to be revisited. I would——

Mr. BARRETT. That gets back to my point. One of the things that the Vice President has talked about is changing where the food inspection is done. I do think that there is a danger here, because you have an agency that is responsible for promoting an industry, an industry that I like. I come from a State with a lot of agriculture in it, and I think it is good that we have an agency that does promotion. But I think that there is a real danger that in your mission to promote this, you are missing part of your other major responsibility which is to make sure that it is safe.

Mr. BRANSTOOL. You know, I don't dispute what you say at all. I would only say that the initiatives that we have outlined, I am hoping that the day will come when the science is there that we can do a better job.

Mr. BARRETT. My final point though is I think you should let the consumers know what you are telling them and what you are not telling them. Because I don't think there is a person in this room who would read this label who would not go away from it and say, "Oh, this is a safe piece of meat," and it isn't. I mean, it may be, but it is not because of anything the government has checked for.

Mr. BRANSTOOL. That is part of the reason we want to have the mandatory safe food handling label that informs the public that the product may contain bacteria that can be harmful.

Mr. BARRETT. Thank you, Mr. Chairman.

[The prepared statement of Mr. Barrett follows:]

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Statement of Representative Tom Barrett (D-WI)
Subcommittee on Human Resources and
Intergovernmental Operations
November 19, 1993

Chairman Towns, thank you for the opportunity to address this committee. Earlier this month, we heard testimony that included a group of parents whose children suffered from the ravages of food poisoning by the E.Coli 0157 H7. Some even lost their children.

I must admit, before this hearing begins, I have a bias in this case. I think we all do. It is impossible for any human being to have heard that testimony and not be moved.

What I want to know is how did this happen? Based on the evidence and the testimony from that hearing, I have to believe that, tragic as it is, these deaths were avoidable.

I've reviewed the material that was submitted by the USDA and I must admit I am deeply, deeply concerned about the goals and priorities of your organization.

How is it possible to balance the goals of consumer protection with those of business promotion? Why do we have one unit handling the conflicting tasks of marketing and inspections? And which goal takes priority when the two inevitably conflict?

I'll put it in terms that you can understand. Look around this room. The television cameras are not here because it's a slow news day. The American public is losing faith in the meat and poultry industries. That means less revenue and fewer jobs. It is in YOUR BEST INTEREST to resolve this problem.

But this is not a matter of simple economics. It's not about market share. Children have died. And I want to know why.

The USDA has repeatedly botched the job and I am putting you on notice, both the General Accounting Office and Vice President Gore's Commission on Reinventing Government have recommended that we need a single entity to ensure the safety of the nation's food supply. And right now the USDA is not looking very attractive.

Mr. TOWNS. Thank you very much. I now yield to Congressman Portman of Ohio.

Mr. PORTMAN. Thank you, Mr. Chairman.

Mr. Barrett raises some good truth in advertising issues, and I will let those go, although they are very interesting.

My questions really go more to your relationship with the slaughter plants and with the packing plants. It seems to me that it is important that the industry and USDA work together closely if we are going to improve the process, and I guess I have a couple questions.

First of all, is there any incentive now, Mr. Branstool, on the part of the industry to go ahead and perhaps implement some of the programs that you have begun in the last 10 months on their own?

Mr. BRANSTOOL. Yes.

Mr. PORTMAN. Are there things we could do to create a further incentive and how is that relationship working between you and the industry?

Mr. BRANSTOOL. Yes, Mr. Chairman, Congressman Portman, you know, I am glad to say that, you know, a good share of industry—you know, there are 6,500 slaughter plants and meat processing plants in the United States and, as I recognize in my testimony, you know, there are some problem plants, and there are some plants that we have closed.

There are also many fine plants, and some plants right now on their own have their voluntary HACCP program. They are also seeking technology to reduce the opportunity for pathogenic contamination.

I was at the University of Wisconsin 2 weeks ago meeting with food toxicologists, microbiologists, experts on foodborne diseases. I toured two modern plants in that State that have already got a HACCP program which we hope to put into place as a mandatory HACCP program for all facilities dealing with meat and poultry. There are any number of industries that are on the cutting edge of this issue as well.

Mr. PORTMAN. Is anything USDA is doing in terms of regulations and inspection of programs and so on discouraging companies from doing things on their own, from voluntary compliance and perhaps even more initiatives and more progressive ways to look at this problem?

Mr. BRANSTOOL. You know, I would hope and I believe that there is no discouragement. Some of the things on the HACCP program we will have learned from those who have already embarked upon that of their own free will.

As long as our requirements are adhered to, you know, any steps that they may want to take that would enhance the opportunity for safety of the products, of course we encourage that, and we have even encouraged companies to even share some of their information.

You know, sometimes you get into a proprietary thing, but we have encouraged companies to share information that they have gathered on pathogens, and I can cite one example. I toured a plant 6 or 7 weeks ago. It was poultry processing plant. And I talked to their person in charge of pathogen reduction, and he told me that

they were sampling for salmonella in chickens, and the amazing thing that they found 2 or 3 years ago was that the incidence of salmonella coming in was far less. They thought possibly 40 percent, but it was like 20 percent if I remember right. But then the scary part of it was to them, by the time they sampled that product at the end of the line, it had almost doubled.

So that told them, it is tough to deal with salmonella coming in on the front end, but when they saw it expand once it started down that line, they knew there was some cross-contamination. So they devised their system to greatly reduce that, and their studies indicated on the other end that then they were able to correct that, but that was part of a HACCP program that allowed that to come to pass.

Mr. PORTMAN. I am encouraged there is feedback.

I looked over this morning the new chart that was provided to us. As an example, on page 3, box 3, under slaughter plant activities, one of your programs is to encourage plants to collect microbiological data and then it says complete it. And I just wondered what the follow through or feedback was.

Are you saying that the encouragement has been completed or that you are actually getting data from these plants now? Or when you say completed, what does that mean?

Mr. BRANSTOOL. I do know, if I could allow our Director of Microbiology, I know that she could enlighten this committee in an important way on that.

Mr. PORTMAN. I guess my point is, simply, I hope we are getting feedback. If you look through a lot of these programs, it indicates to me that a program has been initiated, but there is not necessarily follow through or feedback.

Mr. BRANSTOOL. Many of the initiatives have just been started, or they are ongoing. I think one of our studies—and, again, we have scientists that can be very helpful on this. In the case of steer and heifer study, those steers and heifers that are fed grain as contrasted to dairy cows and older beef cows, you know, I understand that data is coming together. And so some things have been completed. Many things are under way. Some things just began.

Mr. PORTMAN. One other quick question, Mr. Chairman, and that goes to the whole issue of where the responsibility of food safety and inspection should reside. And I know you didn't address that in your testimony directly. It has come up with the last series of questions, but in the NPR there was a suggestion that perhaps there should be an independent agency of some kind, entity of some kind, whether it is in HHS or FDA or elsewhere, independent such as EPA is now. I wonder if the Department could give us the official view as to inspection and if you could expand that answer to include the inspection of fish as well as poultry and meat.

Mr. BRANSTOOL. Mr. Chairman, Congressman Portman, within hours after Secretary Espy was sworn in, the outbreak of E. coli in Washington State and the Northwest seized upon him nearly all of his attention in those early days of leadership as Secretary of the Department. This has been a No. 1 priority with him and with me, and I would say 80 percent of my time is engaged in food safety inspection.

The Vice President, with his effort to streamline our government and reduce duplication, has brought forth for public discussion the question, should all food safety entities and responsibilities be under one umbrella? I believe that is a worthy issue for public discussion.

Our view at the Department of Agriculture is we will be team players. The law has required us to deal with meat and poultry inspection. And until the decision is made, which will be ultimately done by Congress, you know, we will pursue with great diligence improving our meat and poultry inspection.

If the decision is made that it remains in USDA, we will continue that diligence. If it is decided by the Congress that it goes to another agency, independent agency, Food and Drug, wherever, we will work until the day that we don't have that responsibility, and at the time of transition, we will do everything we can to make it as smooth as possible.

Mr. PORTMAN. The agency, Mr. Branstool, doesn't have an official opinion as to whether the inspection responsibilities should continue to reside at USDA?

Mr. BRANSTOOL. No, sir, none other than what I have just articulated.

Mr. PORTMAN. Thank you.

Thank you, Mr. Chairman.

Mr. TOWNS. Thank you very much.

Let me start again with my chicken. On the front we have already established the problems with the wholesomeness seal. Let's go to the back of my chicken. There is a label containing safe handling and cooking instructions on the back. Mr. Branstool, is this a mandated label or a voluntary label? I would be happy to present you with my chicken.

Mr. BRANSTOOL. Yes.

Mr. TOWNS. It is labeled right there. Is that voluntary?

Mr. BRANSTOOL. Yes.

Mr. TOWNS. You can hold my chicken.

Mr. BRANSTOOL. OK, great. It may not live.

Mr. Chairman, this is the safe handling label that right now is not mandated by law because of the court action that I mentioned to you, but this is the label that we want to use to inform the public of proper handling, care and cooking. This is an example of a company that is not required by law to do it at this time but of their own initiative has done that. But that is the label we hope to have in place.

Mr. TOWNS. So that not all meat and poultry products are today required to carry this label. So that is correct. In that case then, I need to applaud this producer of my chicken who voluntarily put the label on.

Mr. MICA. A Mr. Frank Perdue chicken, Mr. Chairman. I checked it out.

Mr. TOWNS. Thank you.

Mr. Branstool, approximately how many people die each year from meat and poultry products contaminated with microbial agents?

Mr. BRANSTOOL. One of the reasons, Mr. Chairman, in our initiative is to have a closer relationship with the Centers for Disease

Control and also the Food and Drug Administration. Does anybody have that number? I don't know that I can quote that number with any degree of authority.

Mr. TOWNS. People do die from eating contaminated meat and poultry products. That is correct, isn't it?

Mr. BRANSTOOL. That is correct.

Mr. TOWNS. The safe handling instructions on my chicken reads, in part, "This product was inspected for your safety. Some animal products may contain bacteria that could cause illness if the product is mishandled or cooked improperly."

First, I want to say that I fully support increasing consumer awareness about proper handling and cooking of food products, but why doesn't the label tell consumers the truth? Shouldn't you put a stamp on the front that says, warning, this animal product may contain bacteria that could cause death or illness if the product is mishandled or cooked improperly?

Mr. BRANSTOOL. Mr. Chairman, you know, we believe that the product when properly handled, it is safe.

Now, if you will remember, years ago, I know when I was a boy, there was concern about trichinosis in pork. There was meat inspection then but, again, there is an example that there is no way that you could identify if, in fact, trichinosis was present in the pork. And when people would eat that pork improperly cooked, then they could become victims of trichinosis themselves, which is a terrible, painful, devastating illness. It is almost that same principle.

The pork could be processed and slaughtered and butchered under the right conditions, but there still was the possibility of trichinosis.

Also with techniques on the farm now, it is still important to cook all meat and poultry. But with other technologies and dealing with rodents and so forth, the trichinosis problem is almost nonexistent. But it still is a potential illness that has been dealt with as the science became available, and so even when that meat was inspected and slaughtered under the proper conditions, no one could say go ahead and handle it as you would want to.

And, again, I go back. That is the reason for the safe food handling label that we are diligently pressing for.

Mr. TOWNS. The safe handling label instructs me to cook this product thoroughly. But that's not very clear. At an earlier hearing a few weeks ago, Janice Sowerby, testified that her 3-year-old son, Scott, died 9 days after eating a sloppy Joe that was cooked thoroughly and then she asked us a very good question. What does cook thoroughly mean? What does cook thoroughly mean on this label?

Mr. BRANSTOOL. You know, to cook thoroughly it would be important that the juices run clear, in other words, not carrying some blood or indication that it is still rare. You know, some people have suggested, well, we ought to have a thermometer in the home, but we had a focus group help us develop the best message that we could in order to be the most effective. The fact is, most people at home probably don't use a thermometer when they are cooking hamburger on the stove. But if the meat is not raw or red or pink and if the juices flow clear, then that is indicative that it is properly cooked.

Mr. TOWNS. I don't want to hog the show here. I see the clock is up. Even though I am the chairman, I don't want to do that.

Mr. Mica.

Mr. MICA. Mr. Chairman, you know, so close to Thanksgiving, it is almost inappropriate that this is going to be known now and for history as the chicken hearing, but I hope it doesn't turn out to be the turkey hearing as far as some of your future activities are concerned, and that is why I am concerned about the approach that you take.

I know both of you I guess are new on the job and coming before this committee. We are concerned about the health and safety of the general public, and we have that responsibility. I believe that some of the things that have been brought up here are essential to performing that task for the public in an effective and cost effective, efficient manner.

You know, there are 250 million Americans just to round it out. Three meals are prepared every day. That is about three-quarters of a billion meals a day and times 365, so there is a lot of opportunity for missteps along the way, whether it is in food preparation or handling or whatever. But I think if you look at voluntary cooperation from industry and you can see here that they are already starting to comply, and you all have the ability to impose cooperation. That is a funny term, impose cooperation, but I think you could get a lot done in that way without a lot of government regulation.

God help us when government is setting the temperature or developing the recipe for hamburger. Research we have already identified as key, and it looks like you have some resources there, so we have adequate tests to ensure the safety of these products.

Public education. I don't think you are doing enough—just my indication from what I have seen, what you have submitted to the committee, and I think I would revisit that if you would, and also some common sense. I mean, a week before Thanksgiving, you don't want to announce your turkey inspection program after that date.

And then the other thing we found here is that some of your inspection procedures do need to be revisited and from the testimony not only today but in the past, you weren't here when some of these abuses took place, but we have some of the same inspectors. Now, I know you have 300 new inspectors so I think some common sense in approach in doing a better job in inspection——

I leave the hearing, too, with the same concern that my colleagues have that some of our labeling is, in fact, misleading. I was surprised to see this wholesome. In fact, this product has been USDA inspected, it says for wholesomeness, but it is a bit misleading and maybe we should go back to that.

The final question I have—and I am going to leave in just a second for another meeting—do you have the people in place now in the agency, both administratively and below, to handle these responsibilities?

Mr. BRANSTOOL. Yes, Mr. Chairman, Congressman Mica. You know, as I also mentioned, we have reorganized our upper echelon people. We are going into the second phase of doing some reorganization, and I must say to you that since I have been here, I feel

real good about the scientists that we have working in the food safety service, and I must say that I feel good about their dedication.

I have a daughter and four sons and seven grandsons and a granddaughter. They have children and grandchildren. You know, we all—nearly all consume meat and, you know, we are pledged to try to find a science-based answer that will work and protect the public.

Mr. MICA. And the final point and question is, you will keep your commitment to provide the information, both to the committee and the chair?

Mr. BRANSTOOL. Yes, sir. Our staff will be contacting your staff to find out what additional information you need by today, and I believe we can have nearly everything by 5 o'clock on Monday.

[The information can be found in appendix 3.]

Mr. MICA. Thank you, Mr. Chairman. I yield back.

Mr. TOWNS. Congressman Portman.

Mr. PORTMAN. Mr. Chairman, I will be brief.

Ms. Jensen has been patiently sitting at the table this morning, and I wanted to ask her one question really out of personal curiosity. In the testimony with regard to the Minnesota situation in October 1988, Mr. Branstool said that the outbreak was caused by consumption of heat processed meat patties that should have been pathogen free when they were distributed from the manufacturing plant. Can you give us a brief description of where the problem was and where, in fact, the pathogens were—did become part of the meat patties?

Ms. JENSEN. Mr. Chairman, Mr. Portman, the actual meat patty did indicate that it had been preheated. What we suspect happened is that as the meat patties went through the processing plant, that maybe the heat equipment was running a little quickly or that the heat itself may not have been adjusted correctly at a certain time. Since Minnesota had that unfortunate situation back in the late 1980's, USDA has promulgated regulations to make sure that that kind of thing does not happen. When you buy a product that says precooked, you make the assumption that it has reached that temperature that protects you. The State of Minnesota worked with USDA, with CDC, with others, and I am happy to say that, as I sit here this morning, a regulation was promulgated to take care of that issue.

Mr. PORTMAN. At the Federal level?

Ms. JENSEN. At the Federal level, yes, sir.

Mr. PORTMAN. I have found the hearing very informative. I have learned a lot.

It seems to me that the bottom line—and this may be obvious—is that visual inspection is not working effectively, at least with regard to E. coli, and we need to expedite some new processes, some new science to come up with other inspection methods.

And as I will just reiterate from my earlier testimony, I hope we are working closely with the industry to be sure that we are encouraging that development. I think it is more cost effective to have industry involved at every stage. I think sometimes it is more efficient and—in terms of results, coming up with processes that work,

and I would hope that the voluntary compliance, as you stated, Mr. Branstool, is something that is assisting USDA in its efforts.

I would also say that you should take this opportunity to tell us what this subcommittee or committee or Congress can do to help you in that process. I know you are testifying before the Senate Agriculture Committee shortly, and you are probably also speaking with our brother on the House Agriculture Committee about this same issue, but I would just like to give you an opportunity briefly if you would like to tell us what we can do for you to make this system work better.

Mr. BRANSTOOL. Yes. You know one thing that I would recommend that, you know, we do have scientists and veterinarians and microbiologists and others, and I know that if there could be a dialog between this committee and our specialists in their respective fields, I am sure they would learn a great deal from you and you would learn a great deal from them. If we revisit what the USDA seal means, you know, that is something that I think should be discussed.

I think the fact that we have worked diligently to get a safe food handling label on the package which is really in a way modifying our seal. We just want to tell people that it has been processed at a plant that is inspected. But when you can't see bacteria, I am willing to revisit that, and if the committee pursues that, we will stand ready to help you any way we can.

Mr. PORTMAN. Thank you.

Thank you, Mr. Chairman.

Mr. TOWNS. Thank you very much.

First of all, Ms. Jensen, let me just say that we are happy that you are on board.

Ms. JENSEN. Thank you.

Mr. TOWNS. We have heard about the fine work that you have done in Minnesota, and we have been informed of that from several sources, so we look forward to working with you, and we know you are new so we didn't bother you today.

Ms. JENSEN. Thank you, Mr. Chairman.

Mr. TOWNS. We know you are brand new, but we do look forward to working with you in the days and months ahead.

Let me just also add that I hope also that when we come back, that we can avoid a compulsory process to obtain the information you have promised to provide us on this Monday. We hope you will be able to voluntarily give it to us without any real problems in that regard, and when we come back to check on you in 6 month's time, we hope that some real progress has been made to reduce the deadly bacteria on meat and poultry. We think it is very important to do it.

Let me also add that, as it was stated on November 4, this committee will continue to review the need to revamp Federal food safety, and we will look at FDA next, so we want to let you know that because we think that this is a very serious issue and that we need to do everything we can to eliminate it.

And, of course, as we talk about health care reform and we talk about 80 million people that get sick each year and the 9,000 deaths, that if we are going to reform health care, we have to look at food safety as well. This is very, very important. When you look

at the costs involved in terms of those illnesses—and we do not know in terms of the exact amount as to how much it costs, but we know that some of them go into the hospital, some of them are out of work, et cetera—a lot of bad things happen.

So if we truly want to take a look at health care, we have to look at every aspect of it, and preventing foodborne illness is a very important aspect of health care reform.

Let me thank both of you for your testimony, and, as I indicated, we hope that you cooperate because we look forward to cooperating with you. I think our objectives and our goals are basically the same.

Mr. BRANSTOOL. Yes, sir.

Mr. TOWNS. So thank you very, very much. This hearing is now adjourned.

[Whereupon, at 11:55 a.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

REINVENTING THE FEDERAL FOOD SAFETY SYSTEM

(Review of FDA's Food Safety Programs)

WEDNESDAY, MAY 25, 1994

HOUSE OF REPRESENTATIVES,
HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:35 a.m., in room 2247, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the subcommittee) presiding.

Present: Representatives Edolphus Towns, Donald M. Payne, Steven Schiff, John L. Mica, and Rob Portman.

Also present: William M. Layden, professional staff member; Martine M. DiCroce, clerk; and Martha B. Morgan, minority professional staff, Committee on Government Operations.

Mr. TOWNS. The Human Resources and Intergovernmental Relations Subcommittee will come to order.

Today the subcommittee continues its review of the Vice President's proposal to reinvent Federal food safety efforts. The subcommittee's hearings last November revealed dangerous flaws in USDA's meat and poultry program. Today we will review FDA's record in protecting the public from unsafe food.

FDA's current visual inspection and end-product testing program is a failure. FDA inspects the Nation's approximately 50,000 food firms on average once every 8 years. That is one inspection every 8 years. FDA inspects less than 8 percent of the over 1 million entries of food imports each year. Infrequent inspections and insufficient product sampling provide no assurance of food safety. At best, FDA can only chase problems after they occur, FDA cannot prevent them from occurring.

FDA has recognized that its inspection program is a failure. In January, FDA proposed a mandatory hazard analysis critical control point program for seafood. Under HACCP, a seafood processor would be required to identify and analyze likely hazards in its process and control these hazards at critical points to prevent them from occurring. FDA would then inspect the processor's records to verify that the controls are working. HACCP is focused on prevention, and I applaud FDA for its leadership in that area. I fully support the HACCP approach.

But there are fundamental questions that need to be answered about whether FDA can make HACCP work. Otherwise, HACCP will be as much a failure as FDA's current inspection system.

First, we received FDA internal documents late last night—the subcommittee did not get them until last night—and they indicate that FDA has deliberately asked for fewer resources than it needs to successfully operate the HACCP program. This means that needless illness will occur and in some instances death.

Second, does FDA have sufficient statutory authority to ensure food safety, that is the question? The subcommittee has found internal FDA documents that clearly state that the agency needs new statutory authority to control food hazards. For example, FDA does not even know who is producing food in this country because food firms are not required to register with FDA.

Third, is FDA sufficiently focused on microbial contamination of food which is responsible for killing over 9,000 people and making up to 80 million sick each year? The subcommittee has found that only 15 percent of the food samples FDA tested in 1993 were analyzed for microbial contamination.

Fourth, is FDA taking sufficient measures to educate and inform consumers, especially those people at greatest risk, about the dangers of microbial contamination? Should FDA require warning labels to inform consumers about the dangers of eating raw shellfish?

Last, what is FDA planning to do to ensure safety of high-risk foods other than seafood? Will these other foods continue to be subject to FDA's failed inspection program?

We need answers to these questions, and we need them right now. People are needlessly dying. Foodborne illness is preventable. And that is a fact.

I believe that the subcommittee's hearings will show that simply changing the organizational boxes will not save lives. Rather, the country needs a comprehensive Federal food safety policy to prevent foodborne illness.

At this time, I would like to yield to the ranking member of the subcommittee, Congressman Schiff from Albuquerque, NM.

Mr. SCHIFF. Thank you, Mr. Chairman. I will be brief because we have a number of witnesses to hear from.

I want to say first that I congratulate you on continuing this group of hearings related to food safety inspection.

Based upon the hearings we have already had, I am inclined to agree with at least the first part of the Vice President's reinventing government proposal, that the food safety inspection service be removed from the Department of Agriculture because it appears to me that there is an inherent conflict of interest in having one agency charged with promoting the sale of U.S. agricultural products on the one hand while it is charged with inspecting and warning the public about difficulties with those same food products on the other.

Further, I think consolidation of many different areas is a good idea simply for the purpose of economy and efficiency, but I think the question for this hearing is the other half of the Vice President's recommendation. If there is such a consolidation, should it be with the Food and Drug Administration, as you have so ably pointed out a moment ago?

There are problems with respect to the Food and Drug Administration's safety program as it now exists, so there is a question about whether consolidation in that agency would be a good idea, or another alternative is if there is to be a consolidation that there be a newly established Federal agency for the purpose of inspecting food, and that is what I hope we will learn more about in this hearing.

I just want to conclude with this one idea. There is a constant disagreement back and forth within the Congress and within the public as to what is the proper role of government, when should government take action, when should government stay out of the picture. We see that debate over and over again in everything from welfare reform to health care reform. I can't imagine, however, an issue in which there is more unanimity than in the public's view that the government has a responsibility to ensure that the food that is sold to the American public is safe to consume.

The public has no way of seeing behind the scenes, so to speak, to know if the food they buy at the supermarkets and restaurants day in and day out is safe for their health and health of their families, and I think that that is an absolute responsibility of the Congress and the administration to provide such security in the purchase and use of food in this country, so I think that you have picked a very important subject to continue here, Mr. Chairman, and I am glad to be supportive of you.

Mr. TOWNS. Thank you, and I would like to thank the gentleman for his very thoughtful statement. At this time I yield to Congressman Mica from Florida.

Mr. MICA. I, too, want to echo the sentiments of my colleague, the ranking member, and thank you for conducting this hearing. It is important both because of the subject and also because of the importance for Congress to follow through, and this is one in a series of hearings we have held on this issue.

Any consumer who believes that the FDA inspected stamp means that their food is safe is sadly mistaken, unfortunately. I am a little bit concerned about the mission of FDA and this administration as it deals with food safety and questions of public health. It seems they have gotten off on tangents of regulating vitamins and legalizing drugs which may not be the real mission of both the administration and FDA. The public, I think, has a right to some guarantee that when they see that food is FDA inspected that it in fact ensures some safety, some concern about health and welfare of the general public, and from our previous testimony and what I have seen presented before us today, that in fact may not be the case.

I have several concerns that I want to follow up on in specific that I think we need to deal with and that aren't addressed. One is the question of the open borders and inspection. With more and more liberalized trading and international commerce activities, I think that we have some very serious questions about food that is imported, and I don't think FDA is meeting their responsibility and public obligation to see that we do have adequate inspection and a quality guarantee. Again, with open borders.

The other area that I am concerned about is in Florida in particular. FDA has yet to set acceptable limits on bacterium in oysters and shellfish, and has now put that decision off I think until

June. In fact, in Florida we have known that there have been problems here for several years, and yet we still see a delay from FDA in getting some type of decision or determination when in fact it is safe.

And finally, our last hearing dealt with turkey, the turkey and poultry question. There again, FDA acted by putting out the turkey report after Thanksgiving on turkey safety. Again, it doesn't appear that they have got their act together either in the inspection program or taking action as needed, and also in a timely fashion to ensure public health safety welfare and information.

So with that, Mr. Chairman, again I commend you, and I have these concerns.

Mr. TOWNS. Thank you very much. Let me thank the gentleman for his statement.

At this time, I would yield to Congressman Payne from New Jersey for any opening statement he might have.

Mr. PAYNE. Thank you, Mr. Chairman.

First of all, let me commend you for calling this very important meeting here and commend you for your leadership on the major health issues that we have been dealing with.

As we all know, food safety is very important to our society. This issue is causing increasing concern. On November 15, 1992, an outbreak of a potentially deadly and infectious strain of E. coli broke out that lasted through February 28 of last year, causing more than 500 illnesses and 4 deaths in 4 Western States. This outbreak was linked to undercooked hamburgers from the fast food chain Jack In The Box.

Last fall, this subcommittee began looking into the Vice President's recommendation to consolidate all food safety and inspection functions to the Food and Drug Administration. Currently, this responsibility is shared with the Department of Agriculture, which is responsible for meat and poultry.

At that hearing, we uncovered some disturbing practices in the meat inspection process. Every year over 6 million people become sick from foodborne diseases. Those particularly vulnerable are infants, children, and the elderly, people for whom we must go the extra mile to protect.

As a matter of fact, many nations are judged in the manner in which they provide for their young and their elderly. The ramifications for individuals whose immune systems are compromised are extremely dangerous because their systems are not equipped to fight these contagious diseases.

While thoroughly cooking seafood will virtually get rid of harmful microbes, some seafood products are consumed raw, as we all know, and do pose very serious potential health risks to the public. In fairness to the FDA, they recognize that the current inspection process is not adequate to meet the existing needs. They have proposed instituting a new procedure to ensure the safety of our seafood supply. It is called the hazard analysis critical control point, that is kind of a tongue twister. You all know what it is.

By identifying hazards at critical points in the inspection process, this approach would control and prevent potential outbreaks. I hope the issue that we examine here will increase public awareness of the inadequacy of our food safety inspection process and that we

will exercise our appointed responsibilities to ensure a safe food supply.

Mr. Chairman, I just wanted to point out that your article in Monday's Roll Call was excellent, and that I am encouraged to see that the subcommittee is looking closely at this issue before it becomes critical.

I would like to thank you again for your leadership in calling this very important hearing today. As you know, our Nation and its food supply is one of our greatest resources. We are very protected by FDA and other agencies that ensure in the past that what we consumed was proper and safe, and so I think that this hearing is extremely important and, once again, let me commend you for your leadership in this area. Thank you.

Mr. TOWNS. Let me, first of all, begin by thanking the gentleman for his statement, but let me especially thank him for his kind words.

At this time, I would like to say to the witnesses, all the witnesses, that your entire statements will be included in the record, and when the red light comes on we would like you to please conclude.

Let me begin by asking Mr. John Harman, Director of Food and Agriculture Issues, U.S. General Accounting Office; and Caroline Smith DeWaal, director of legal affairs at Public Voice for Food and Health Policy to please come forward. Let me ask all of you if you would stand. It is the custom of this committee to swear in our witnesses.

[Witnesses sworn.]

Mr. TOWNS. Let the record show that the witnesses answered in the affirmative.

Why don't you begin, Mr. Harman.

STATEMENT OF JOHN W. HARMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY EDWARD ZADJURA, ASSISTANT DIRECTOR

Mr. HARMAN. Thank you, Mr. Chairman.

Before I begin I would like to introduce Ed Zadjura who I have asked to join me at the table this morning. Ed has been intimately involved in our work in this area for the last 5 or 6 years.

We are pleased to be here again to discuss the need to reinvent the Federal food safety system. In previous reports over the years, and we have issued many, as well as testimonies, we have stated that fundamental changes are needed to this system including moving to a uniform scientific risk-based system.

As you requested, we will also discuss our views on where the food safety responsibility should reside in the Federal Government. As you mentioned, our entire testimony has been submitted for the record.

In summary, the current food safety system hampers and impedes efforts to address public health concerns associated with existing and newly identified food safety risks. The system was not developed under any rational plan but evolved over many years to

address specific health threats from particular food products and has been slow to respond to changing health risks.

Efforts to address food safety concerns continue to be hampered by inconsistent and inflexible oversight and enforcement authorities, inefficient resource use, and ineffective coordination.

In previous reports and testimonies, we concluded that the most effective way for the Federal Government to resolve longstanding problems, deal with emerging food safety issues, and ensure a safe food supply is to create a single food safety agency responsible for administering a uniform set of laws.

While we believe that an independent Federal food safety agency, operating much like the Environmental Protection Agency, is the preferred approach, we recognize that there are problems associated with setting up a new government agency and, therefore, consolidating food safety activities under an existing department right now looks to us to be a more likely scenario.

While the question of an independent single agency versus an existing department is a matter of judgment upon which opinions can differ, consolidating such activities under the Department of Agriculture or the Department of Health and Human Service's Food and Drug Administration has its own set of problems that must be overcome.

In November 1993, we testified before this subcommittee that food safety inspections should not be consolidated under USDA because of a real or perceived conflict of interest with its role of promoting agriculture. Moving responsibility for all food safety to agriculture would likely compound this problem. However, while FDA has a clear public health mission and thus is free of institutional conflicts, we believe that before food safety activities can be consolidated under FDA, other actions would need to take place, including providing adequate resources and enforcement authorities to perform its responsibilities.

Regardless of where a single agency is housed, what is most important are certain principles, including a clear commitment by the Federal Government to consumer protection, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency. Although these principles can be influenced by organizational placement, commitment to them probably depends more on public and political concern with the importance of the mission.

In any event, basic long-term improvements in food safety, and I think this is very important, it is a point we have made over and over again, these basic long-term improvements will likely not occur unless fundamental legislative and structural changes are made to the entire system. This requires that current food safety legislation be revised to make it uniform, consistent, and risk based.

That completes my summary, Mr. Chairman. We will certainly be glad to answer any questions that you or the Members may have.

Mr. TOWNS. Thank you very much, Mr. Harman.

[The prepared statement of Mr. Harman follows:]

United States General Accounting Office

GAO

Testimony

Before the Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives

For Release on Delivery
Expected at
9:30 a.m. EDT
Wednesday
May 25, 1994

FOOD SAFETY

A Unified, Risk-Based Food Safety System Needed

Statement of John W. Harman,
Director, Food and Agriculture Issues,
Resources, Community, and Economic
Development Division

GAO/T-RCED-94-223

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the need to reinvent the federal food safety system. In previous reports and testimonies, we have stated that fundamental changes are needed to this system, including moving to a uniform, scientific, risk-based system. As you requested, we will also discuss our views on where food safety responsibilities should reside in the federal government.

In summary, the current food safety system hampers and impedes efforts to address public health concerns associated with existing and newly identified food safety risks. The system was not developed under any rational plan but evolved over many years to address specific health threats from particular food products and has been slow to respond to changing health risks. Efforts to address food safety concerns continue to be hampered by inconsistent and inflexible oversight and enforcement authorities, inefficient resource use, and ineffective coordination. In previous reports and testimonies, we concluded that the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure a safe food supply is to create a single food safety agency responsible for administering a uniform set of laws.[1]

While we believe that an independent federal food safety agency, operating much like the Environmental Protection Agency (EPA), is the preferred approach, we recognize that there are problems associated with setting up a new government agency and, therefore, consolidating food safety activities under an existing department is a more likely scenario. While the question of an independent single agency versus an existing department is a matter of judgment upon which opinions can differ, consolidating such activities under the U.S. Department of Agriculture (USDA) or the Department of Health and Human Service's (HHS) Food and Drug Administration (FDA) has its own set of problems.

In November 1993, we testified before your Subcommittee that food safety inspections should not be consolidated under USDA because of a real or perceived conflict of interests with its role of promoting agriculture.[2] Moving responsibility for all food safety to agriculture would likely compound this problem. However, while FDA has a clear public health mission and thus is free of institutional conflicts, we believe that before food safety

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[1]Our testimony is based on over 60 reports and studies issued over the last 25 years by GAO, agency Inspectors General, and others. (See app. I for a listing of GAO and other reports).

[2]Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety, (GAO/T-RCED-94-71, Nov. 4, 1993).

activities could be consolidated under FDA, other actions would need to take place, including providing FDA adequate resources and authorities to perform its responsibilities. Regardless of where such an agency is housed, the current food safety legislation needs to be revised to make it uniform, consistent, and risk-based.

Before we discuss the results of our work in more detail, some brief background information may be useful.

BACKGROUND

The current federal food safety system consists of as many as 35 different laws administered by 12 agencies. Two agencies account for most federal food safety spending: FDA is responsible for the safety of most foods and the Food Safety Inspection Service (FSIS), under USDA, is responsible for the safety of meat and poultry products.

Despite $1 billion spent annually on the current food safety system, food safety remains a concern. Because many cases of foodborne illness go undiagnosed, the actual number of incidents is probably much higher than the conservative estimate of 6.5 million annually and, according to the Centers for Disease Control, may reach 80 million or more. While it is not possible to put a dollar figure on the pain and suffering caused by foodborne illness, efforts have been made to quantify the economic costs. For example, FDA and FSIS have estimated that the medical costs and lost productivity from foodborne illness total $17 billion to $23 billion per year.

CURRENT FEDERAL INSPECTION PROGRAM HAS SIGNIFICANT LIMITATIONS

During the past 20 years, other organizations--most recently, the Vice President's National Performance Review Team--have issued reports detailing problems with the federal food safety system and made numerous recommendations for change. While many of these recommendations have been acted on, improvement efforts have fallen short largely because the agencies continue to operate under different regulatory approaches contained in their basic laws. Consequently, it is unlikely that basic, long-term improvements in food safety will occur unless fundamental legislative and structural changes are made to the entire food safety system.

The federal regulatory system did not develop under any rational plan. As the understanding of foodborne hazards grew, food safety concerns changed. Addressing one new worry after another, legislators amended old laws and enacted new ones. Programs emerged piecemeal, typically in response to particular health threats or economic crises. The laws not only assigned specific food commodities to particular agencies but also provided the agencies with different authorities and responsibilities,

reflecting significantly different regulatory approaches. As a result, inflexible and inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts, have hampered and continue to impede efforts to address public health concerns associated with existing and newly identified food safety risks. The following examples represent some of the problems we have found.

-- Firms that process food products that pose similar health risks to the public are inspected at widely different frequencies, depending on which agency--and thus which regulatory approach--governs them. Although there is virtually no difference in the potential health risk, meat and poultry plants regulated by FSIS are inspected at least daily, while firms that process rabbit, venison, and quail, for example, which are under FDA's jurisdiction, were inspected at an average rate of about once every 3 to 5 years in 1992.

-- Responsibilities for oversight of chemical residues in foods are fragmented among EPA, FDA, and USDA. As a result, chemicals posing similar risks may be treated differently by the agencies because they operate under different laws and regulations.

-- Enforcement authorities granted to the agencies also differ. USDA agencies have the authority to (1) require food processors to register so that they can be inspected, (2) presume that food firms are involved in interstate commerce and are thus subject to regulation, (3) prohibit the use of processing equipment that may potentially contaminate food products, and (4) temporarily detain any suspect foods. Conversely, FDA, without such authority, is often hindered in its ability to oversee food processors.

-- Federal agencies are not using their inspection resources efficiently. Because the frequency of inspection is based on the agencies' regulatory approach, some foods and establishments may be receiving too much attention while others may not be receiving enough. What constitutes an appropriate level of inspection has been a long-standing issue in connection with FSIS' daily inspection requirement for meat and poultry processing plants when compared with FDA's inspection interval of once every several years. Furthermore, food establishments are sometimes inspected by more than one federal agency because they participate in programs or process foods that are under the jurisdiction of different agencies.

-- Agency coordination agreements aimed at overcoming the fragmented federal food safety system by avoiding duplication and/or gaps in coverage are ineffective.

Unsanitary and other unsafe conditions have persisted in food processing plants because notifications required by the coordination agreements do not always take place or the problems referred to the responsible agency are not always promptly investigated. While the agencies have agreed to update the agreements, history has shown that as time passes the agreements become outdated and ineffective.

CONSOLIDATION OF FOOD SAFETY AGENCIES IS A LONG-STANDING ISSUE

Consolidating food safety activities is not a new concept. Such a concept was debated in 1972 in connection with a proposed bill to transfer FDA's responsibilities, including its food safety activities, to a new independent agency, called the Consumer Safety Agency. This new agency was to be responsible for, among other things, ensuring the safety of the nation's food supply, although meat and poultry inspection was to remain in USDA.

Our position today is similar to the one we voiced in 1972, when we testified that whether an independent single agency was preferable to a component of an existing department was a matter of judgment upon which opinions can differ.[3] While today we believe a single independent food safety agency is the preferred approach, we recognize the difficulties in establishing a new government agency. Regardless of where a single agency is housed, what is most important as we reasoned in 1972, were certain principles, including: a clear commitment by the federal government to consumer protection, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency. Although these principles can be influenced by organizational placement, commitment to them probably depends more on public and political concern for the importance of the mission.

We also still believe, as we testified in 1972, that it is important for the food safety mission to be housed in an agency that is not charged with responsibilities that might conflict, or appear to conflict, with its willingness to aggressively administer its public health protection responsibilities. Although the Secretary of Agriculture had established a separate agency dedicated to meat and poultry inspection and related consumer protection functions, the agency still remained in a department having a principal mission of promoting and serving the agriculture industry. We suggested then that such activities be given to a new independent agency or an existing agency not in USDA in order to consolidate similar functions, allow flexibility in the use of

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[3]Hearings on the Consumer Safety Act of 1972 before the Subcommittee on Executive Reorganization and Government Research, Senate Committee on Government Operations, (1972).

resources, and eliminate overlapping activities. Establishing a new independent agency because of conflicting interests is not unprecedented. In 1974, the Congress established the Nuclear Regulatory Commission, an independent agency, thus eliminating the Department of Energy's dual responsibility for promoting and regulating nuclear power.

Even though the meat and poultry inspection responsibilities were transferred to the current Food Safety and Inspection Service in 1981, they remained, as they do today, in USDA, which has the dual responsibility of promoting agriculture and protecting the consumer. While there are a number of proposals to reorganize USDA to separate its food safety and agriculture promotion responsibilities, they would still be housed under a department with conflicting roles. Conflicting interests or interference by the USDA Secretary's office have been cited by some groups and individuals, including two former FSIS Administrators and a former USDA Assistant Secretary, as one of the reason's why we need an independent food safety agency. Such conflicts and interferences tend to reduce public confidence in the federal government's ability to ensure the safety of the nation's food supply. Consolidating all food safety responsibilities in USDA would only compound this problem since the agency is involved in various ways in promoting or supporting production of most food products.

FDA'S FOOD SAFETY PROGRAM HAS SERIOUS WEAKNESSES

While FDA has a clear public health mission and thus does not have the potential institutional conflict-of-interest problem of USDA, FDA has a different set of problems that would need to be addressed if federal food safety activities were consolidated under its jurisdiction. FDA itself has recognized the limitations of its food safety programs. In a March 12, 1993, memorandum to the Secretary of HHS, the FDA Commissioner outlined the major problems with the federal food safety system and what needed to be done to strengthen the system, including the need to provide FDA adequate resources and enforcement authorities to perform its responsibilities. The Commissioner's analysis is consistent with some of the problems we have reported in the past, including limited resources to carry out its mission and a lack of some necessary authorities. According to senior FDA officials these problems plague the agency today.

FDA Has Limited Resources

The level of effort to protect the food supply has simply not kept pace with the increasing size and complexity of the food industry and food imports. In September 1989 and again in July 1993, we reported that FDA's resources have not kept pace with its

responsibilities.[4] Since 1980, FDA's legislatively imposed responsibilities have greatly increased while at the same time it has had to deal with public health crises, such as the AIDS epidemic and product-tampering incidents which have placed added demands on its resources. In spite of these increased demands, FDA's staffing levels declined during the 1980s from a high of 7,816 staff years in 1980 to a low of 6,855 staff years in 1987 but have increased to 8,900 staff years in 1993. However, while FDA has received additional resources, the vast majority of the increases were devoted to FDA's nonfood activities, such as approval and oversight of drugs and medical devices. (See app. II for details on FDA's resources, inspections, samples, and enforcement actions.)

Although FDA has devoted some additional resources over the past few of years to food activities, such as the resources needed to inspect all seafood plants and develop a plan for ensuring the safety of seafood products, resource constraints continue to affect its ability to oversee the food industry. FDA officials said that limited resources, public health emergencies, and other high-priority tasks, such as inspections of blood banks, preclude it from inspecting as many domestic food establishments as it would like. For example, according to the Commissioner's letter to the Secretary of HHS, FDA's resources have dropped to a level where the agency can only inspect food processing facilities on average about once every 8 years.

Former FDA officials and representatives of industry, consumer groups, and academia have also maintained that a large disparity exists between FDA's responsibilities and resources. For example, the number of new food products introduced annually to the retail grocery market has more than quadrupled--from just over 2,000 in 1980 to over 12,000 in 1992--and the number and variety of new food products will continue to increase as industry expands its technological capacity.

FDA Needs Additional Enforcement Authorities

Limitations in existing FDA authority to monitor food firms and take enforcement actions may affect the agency's ability to ensure food safety. In addition to the previously discussed authorities granted USDA but not FDA, FDA lacks the authority to access manufacturers' production and distribution records and impose civil penalties for violations. The need for additional authorities was recommended in the May 1991 Final Report of the Advisory Committee on the Food and Drug Administration (frequently

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[4]FDA Resources: Comprehensive Assessment of Staffing, Facilities, and Equipment Needed, (GAO/HRD-89-142, Sept. 15, 1989) and Food Safety and Quality: Innovative Strategies May Be Needed to Regulate New Food Technologies, (GAO/RCED-93-142, July 26, 1993).

called the Edwards Committee in recognition of the Committee Chairman, Charles C. Edwards, M.D.).

In our 1993 report on new food technologies, we said that the lack of authority to access food plants records may affect FDA's plans to adopt an inspection approach based on the hazard analysis and critical control point (HACCP) concept. Under HACCP, each plant identifies and establishes a system to monitor, by physical observation or chemical analysis, the critical control points in its process to ensure that they are effective. Plant personnel document the results of their monitoring efforts and when a control point is found to be ineffective the line is immediately stopped and corrective actions implemented. However, without access to plant production and HACCP records, FDA would be unable to verify plant compliance with HACCP requirements.

Furthermore, FDA does not have the authority to review plant shipping documents, which limits its ability to track and remove food products found to be adulterated from the market place.

In September 1992 and June 1993, we reported on FDA's need for civil penalty authority to deter importers from abusing food safety regulations.[5] While most importers comply with FDA's instructions and properly destroy or export adulterated shipments, a few repeatedly fail to do so. Rather than destroy or export adulterated food products, some importers choose to distribute them into the U.S. market and pay the relatively low damage assessments. In our September 1992 report, we stated that in the four FDA districts we reviewed, importers did not destroy or export, as required, about one-third of the imported foods in which FDA detected prohibited pesticides. Furthermore, 10 importers were responsible for illegally distributing 64 percent of the 336 adulterated shipments.

Although FDA could criminally prosecute such offenders, these cases have low priority for Department of Justice prosecution. In addition, punitive damages are based on bond amounts that are set for purposes other than enforcement of FDA regulations. As a result, in September 1992 and again in June 1993, we suggested that the Congress give FDA the authority to levy civil administrative penalties to eliminate an importer's economic incentive to sell adulterated foods rather than destroy or export those foods. Similar recommendations have been made by the FDA Commissioner, the Edwards Committee, and others. Although legislation has been introduced to address these issues, it has not been enacted.

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[5]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves, (GAO/RCED-92-205, Sept. 24, 1992) and Pesticides: Status of FDA's Efforts to Improve Monitoring and Enforcement, (GAO/T-RCED-93-55, June 16, 1993).

CONCLUSIONS

The current food safety system's inflexible and inconsistent oversight and enforcement authorities, inefficient resource use, and ineffective coordination efforts, hampers and impedes efforts to address public health concerns associated with existing and newly identified food safety risks. The nature of the threat to public health from food products has changed over time, but the food safety system has not adjusted accordingly. The adoption of a risk-based approach to inspections could lead to safer products and reduced costs as scarce resources are redirected from low-risk operations to high-risk areas that require greater coverage.

Past efforts to correct deficiencies of the federal food safety inspection system have fallen short because the responsible agencies have continued to operate under different food safety statutes. To obtain a uniform, risk-based inspection system, basic changes need to be made to the current regulatory system. In our view, creating a single food safety agency is the most effective way for the federal government to resolve long-standing problems, deal with emerging food safety issues, and ensure the safety of our country's food supply.

Given the problems associated with establishing a new agency, consolidating food safety responsibilities under an existing department is a more likely scenario, although such an option has its own set of problems. USDA has conflicting interests that undermine public confidence in the federal government's ability to ensure a safe food supply, and FDA's food safety program has serious weaknesses that need to be addressed before giving it additional responsibilities.

Regardless of where a single food safety agency is located, there needs to be a clear commitment by the federal government to public health protection, adequate resources devoted to that purpose, and competent and aggressive administration of uniform food safety laws.

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Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions.

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ON THE FEDERAL FOOD SAFETY INSPECTION SYSTEM SINCE 1969

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Pesticides: Status of FDA's Efforts to Improve Monitoring and Enforcement (GAO/T-RCED-93-55, June 16, 1993).

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APPENDIX I

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FDA'S RESOURCES AND ACTIVITIES

The Food and Drug Administration (FDA) is not only responsible for regulating foods it is also responsible for cosmetics, human drugs, biologics, medical devices, radiological health, and animal drugs and feeds. For the most part, FDA is organized into centers, such as the Center for Food Safety and Applied Nutrition, that are generally associated with its responsibilities. Table 2.1 provides resource, inspection, sample, and enforcement action information on FDA's foods responsibilities.

Table 2.1: FDA staffing levels, inspections, microbiological samples analyzed, and enforcement actions.

Fiscal Year	Total FDA Staff Years	Foods Staff Years (a)	Foods Inspec -tions (b)	Foods Sample (c)	Foods Enforce -ments (d)
1993	8,900	2,695	13,961	8,161	1,010
1992	8,792	2,793	14,655	8,778	1,036
1991	8,267	2,637	17,151	7,939	761
1990	7,629	2,475	14,309	7,593	836
1989	7,228	2,377	15,331	7,059	679
1988	7,103				646
1987	6,855				1,444
1986	6,904				2,219
1985	7,094				1,176
1984	7,172				906
1983	7,219				515
1982	7,085				
1981	7,467				
1980	7,816				

Notes:

[a]Food staff years comprise the staff years devoted to foods by the Center for Food Safety and Applied Nutrition and the field staff of the Office of Regulatory Affairs.

[b]Food inspections comprises both FDA staff inspections and contracted inspections of domestic food plants.

[c]Food samples comprises microbiological samples of domestic and imported foods.

[d]Enforcements are seizures, recalls, warning letters, injunctions and prosecutions.

Source: GAO presentation of FDA data.

(150629)

Mr. TOWNS. Ms. DeWaal.

STATEMENT OF CAROLINE SMITH DeWAAL, DIRECTOR, LEGAL AFFAIRS, PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Ms. DEWAAL. Thank you. Mr. Chairman and members of the committee, good morning. My name is Caroline Smith DeWaal. I am director of legal affairs for Public Voice for Food and Health Policy. Thank you very much for the opportunity to testify this morning on the need to improve the Federal food safety system.

Food safety is a critical but poorly addressed public health problem. Despite the Federal Government spending over $650 million each year to ensure food safety, needless illnesses and deaths from foodborne illnesses happen all too often. At Public Voice's 1993 national food policy conference, FDA Commissioner David Kessler said, "The history of food safety regulation is filled with government watchdogs chasing the horses after they have left the barn."

Dr. Kessler quite aptly highlights that FDA's regulatory authority for food is limited for the most part to finding rather than preventing adulterated food. One outcome of this system is lagging consumer confidence in the highest risk food product that FDA inspects, and that would be seafood. These consumer concerns are well justified. Let me give you just a few examples that we are aware of, of public health problems with seafood.

Since 1992, at least 13 people have died in just one State, that is Florida, from consumption of raw shellfish. Consumers in many other States where shellfish is shipped are also at risk. The last death in Florida occurred just 1 month ago today on April 25. It was a Wisconsin woman with diabetes. The culprit is a common marine bacteria that can be fatal to certainly medically compromised individuals, such as those with diabetes, AIDS, cancer, liver and kidney disease, blood disorders, and even alcoholics.

In another incident last November, just before Thanksgiving, FDA had to issue a national alert advising consumers, all consumers, not just high-risk ones, urging them not to eat any oysters coming from certain Louisiana harvesting areas. This was in response to a major outbreak in which over 150 people became ill, and this was a problem that was not addressed by cooking the oysters. Even if the oysters were cooked, there was still a problem.

There are many other examples of outbreaks of illness involving fish as well as shellfish. Today I am mostly focusing on shellfish. The reason is that in 1991 Public Voice called on FDA to take immediate action to mandate a warning label for packages of raw shellfish that are sold in your local supermarkets, they are sold in packages like this, also point-of-purchase sales for restaurants or deli counters, things like that where raw oysters are also sold.

Since 1991, the FDA has failed to act on our request, and we have renewed that call today. The agency has taken another step to address the consumer concerns about seafood safety, however.

In January, Secretary Donna Shalala and Commissioner Kessler announced their proposal to utilize a new food safety management system for seafood processors called hazard analysis critical control points, or HACCP. HACCP is a critical needed first step to improve seafood safety. However, despite HACCP's promise, there are significant weaknesses in FDA's proposed regulation, weaknesses that

are largely due to the agency's chronic lack of resources and authority for food safety.

Unfortunately, FDA's current seafood inspection program is so inadequate that it threatens to undermine effective implementation of HACCP. Ultimately without a significant increase in FDA's field staff, inspection frequency will decline under HACCP. Records inspection will prove to be an overwhelming task and HACCP will become an unenforced industry honor system. This outcome would cripple public confidence in this promising new technology to promote food safety.

Here are a few of our concerns about FDA's implementation of HACCP. First, FDA's inspections of seafood processing plants will decrease under HACCP. Current inspection frequency, which is totally inadequate given the risks of this product, are once every 1 to 3 years. During HACCP implementation, that frequency will be reduced to once every 2 to 6 years.

I am going to wrap up.

Vice President Gore has identified critical inconsistencies for food safety. We believe that although FDA has a strong public health mission, one that we would like to recognize and support, without significant inspection and enforcement resources, they should not be given additional authority. Thank you.

Mr. TOWNS. Thank you very much.

[The prepared statement of Ms. DeWaal follows:]

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TESTIMONY OF CAROLINE SMITH DEWAAL,
Director of Legal Affairs
PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Before the

HOUSE COMMITTEE ON GOVERNMENT OPERATIONS
Subcommittee on Human Resources and
Intergovernmental Relations

Regarding

The Need to Revamp the Federal Food Safety System
Seafood Safety and the Impact of HACCP

Good morning, Chairman Towns and members of the Committee. My name is Caroline Smith DeWaal and I am Director of Legal Affairs for Public Voice for Food and Health Policy. Public Voice is a national nonprofit research, education and advocacy organization working to ensure an affordable, safe and nutritious food supply that is produced in a manner that protects the environment.

Thank you for the opportunity to testify on the need to improve the federal food safety system. Food safety is a critical, but poorly addressed public health problem. Despite spending well over 650 million dollars per year to ensure the safety of the food supply, needless illnesses and deaths from food-borne illness happen all too often.

Seafood provides an excellent example of a food product that suffers from the federal government's inability to deliver a proactive, effective food safety program. Seafood is not subject to comprehensive mandatory federal inspection. Instead, seafood processors are visited by FDA inspectors once a year, at best.

This January, FDA published a proposed rule to mandate a new program called "Hazard Analysis Critical Control Points" or "HACCP" for seafood processors that promises to deliver safer seafood products. Despite HACCP's promise, there are significant weaknesses in FDA's proposed regulation, weaknesses that are largely due to the agency's chronic lack of resources and

authority for food safety. If FDA's HACCP program is to succeed in giving consumers safer seafood products, these weaknesses must be addressed. At a minimum, additional inspection resources are critical to assure public confidence in HACCP as a tool to assure food safety.

FDA's ability to oversee food safety is compromised by inadequate resources and authority

The Food and Drug Administration has responsibility for assuring the safety of all domestic and imported food products other than meat, poultry and eggs. However, the regulatory tools that FDA has at its disposal to accomplish this mission are inadequate. Even Food and Drug Commissioner David Kessler recognizes the limits to his agency's ability to ensure food safety. At Public Voice's 1993 National Food Policy Conference, Kessler said: "The history of food safety regulation is filled with government watchdogs chasing the horses after they've left the barn."[1]

Dr. Kessler quite aptly highlights that FDA's regulatory authority for food is limited for the most part to finding rather than preventing adulterated food in the market. Unlike USDA's meat and poultry inspection program, with the resources to place full-time government inspectors in processing plants, FDA uses a fraction of the resources to try to catch adulterated foods at processing plants during infrequent visits. One outcome of this system is lagging consumer confidence in the highest risk food product that FDA inspects -- seafood.

Between 1988 and 1993, the number of consumers who reported that someone in their household had gotten sick from seafood doubled from 7% to 14%, according to an FDA-sponsored telephone survey.[2] During the same period, there was a two percent decline, from 22% to 20%, in those who blamed meat as a source of food borne illness in their household and a one percent increase, from 11% to 12%, in those who blamed poultry. In another major survey of consumer attitudes to food safety, the Food Marketing Institute's 1992 Trends Report, a 10% decline in consumer's

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[1] Statement of Dr. David Kessler, Commissioner of the Food and Drug Administration, Public Voice's National Food Policy Conference, March 22, 1993.

[2] Preliminary results of a food safety survey conducted by FDA Consumer Studies Branch, Division of Marketing Studies. These results were based on a telephone survey of 1620 consumers in March 1993. The survey was a follow-up to a 1988 health survey. Reported in Food Chemical News, September 20, 1993, p. 48.

confidence in food safety, from 82% in 1991 to 72% in 1992, was attributed to concerns about seafood.

These consumer concerns are well justified. Here are just a few examples of recent public health problems with seafood:

* Since 1992, at least 13 people have died in one state, Florida, from consumption of raw shellfish products. The last death occurred just one month ago, in late April. And FDA estimates that there are 48 such cases per year, an estimate that we think is much too low. The culprit is a common marine bacteria that can be fatal to certain medically compromised individuals, such as those with AIDS, cancer, diabetes, liver and kidney disease, blood disorders and alcoholics. Most of these deaths could have been prevented with adequate consumer education. However, despite the fact that Public Voice has called on FDA to mandate a warning label for raw shellfish products since 1991, the agency has failed to act. Meanwhile, the death watch continues.

* In November, 1993, just before Thanksgiving, FDA issued a nationwide alert advising consumers not to eat any oysters coming from certain Louisiana harvesting areas in response to a major outbreak in which over 150 people became ill. Apparently concerned about holiday use of oysters, the agency gave consumers the following well worn advice, "When in doubt, throw it out." The alert covered oysters in the shell, shucked, fresh and frozen.

* FDA allowed a type of fish, called escolar, to be sold in the Washington area despite the fact that it was known to cause severe diarrhea. A physician employed at the National Institute of Health purchased the fish and personally experienced its effects. According to a report from the Washington Post in May 1992, the fish was only pulled from the market after the physician, who was concerned about the health implications for children and the elderly, reviewed the scientific literature and notified the FDA. FDA then notified restaurant and trade groups, requesting that they notify their members to stop selling the fish. According to the Post, some local grocery stores were never notified and continued to sell the product.

* In April and May 1992, there were 79 reported cases of scombroid poisoning from fresh tuna in five states. The implicated tuna was imported from Ecuador. According to a CDC memo, the FDA was aware of tuna illness outbreaks as early as May 1 but the agency made no effort to alert consumers and waited until late May to formally alert the states. Only one state issued a consumer alert.

These examples are just the tip of the iceberg. The Centers for Disease Control reported at a Congressional hearing last June that seafood illnesses accounted for 20 percent of all reported outbreaks of food poisoning and 5 percent of all outbreak-associated cases reported to CDC between 1973 and 1991.

The impact of HACCP

In an effort to address consumer concerns about seafood safety, in January, Secretary Donna Shalala and Commissioner David Kessler announced their proposal to utilize a new food safety management system for seafood processors called HACCP ("Hazard Analysis Critical Control Points"). HACCP is a critically needed first step to improve seafood safety. Ultimately, industry-developed and -administered HACCP will supplement and complement the efforts of FDA to regulate the seafood industry.

Unfortunately, FDA's current inspection program for seafood processors is so inadequate that it threatens to undermine effective implementation of HACCP. The agency's claims that it has adequate resources to successfully manage a HACCP program cannot be substantiated. At present, FDA's field staff is not large enough to conduct frequent inspections of all seafood processing plants. This shortage in personnel will create unacceptable delays in HACCP plan approval and post-approval implementation. Ultimately, without a significant increase in FDA's field staff, inspection frequency will decline, records inspection will prove an overwhelming task, and HACCP will become an unenforced industry honor system. This outcome would cripple public confidence in this promising new technology to promote food safety.

FDA's inspections of seafood plants will decrease under HACCP

FDA's total field resources for seafood is handled by approximately 400 employees, including both inspectors and field support staff for both domestic and imported seafood.[3] The agency uses this force to inspect over 5000 domestic processing plants and facilities and all ports of entry for the products. According to FDA, the field staff inspects 1000 high-risk seafood

[3] Discussion with Bob Miller, FDA Budget Analyst, May 3, 1994. Mr. Miller said that the seafood-related field resources for FY 1993 was 388 full time equivalent employees (FTEs). This includes inspectors, field offices and overhead, lab work, research test method development, wharf examinations, etc.

processing plants once a year, and all others once every two to three years.[4] Current plant and processing inspections average 20 hours per plant.

Tom Billy, Director of FDA's Office of Seafood, stated recently that the initial approval of HACCP plans will likely take 40 inspection hours, double the current time. He said that this would reduce the frequency of FDA's inspections.[5]

If inspections are reduced by 50 percent to accommodate the lengthy initial inspection to approve the HACCP plan, the average processor will be visited once every five to six years during HACCP's implementation phase. Even the 14,000 processors that FDA considers high risk (i.e. those that prepare cooked ready-to-eat products, scombroid species and smoked fish) will face a decline in inspection frequency while HACCP is being implemented. Based on Billy's estimates, FDA's inspection of high risk processors will probably decrease in frequency from once per year to once every two years. This level of inspection is clearly inadequate, given the potential health hazards of the products that are being inspected.[6]

HACCP records review will be nearly impossible unless inspection resources are dramatically increased

Mandatory HACCP will require that seafood processors document their monitoring of both sanitation and HACCP checkpoints. Review of these monitoring records should be an integral component of FDA's inspection of processing plants, providing the agency with verification that HACCP is being

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[4] Compare this intensity of inspection with meat and poultry processors who have continuous inspection or at a minimum daily plant inspections.

[5] Statement of Tom Billy, Director of FDA's Office of Seafood, Baltimore public meeting on HACCP, February 22, 1994.

[6] Canada has a much more sophisticated rating system for seafood processors as well as more frequent inspections. "Excellent" plants are inspected once every two months, "good" plants are inspected every month, "satisfactory" plants are inspected every two weeks and "fail" plants are asked to shut down until the deficiencies are corrected. "Canada May Share Computerized Seafood Information With U.S.," Food Chemical News, Vol. 35, No. 29, September 13, 1993, p. 23-24.

properly implemented.[7] However, without additional inspection resources, record inspection by FDA will be negligible.

If the average plant has five critical control points (CCPs) and three sanitation points[8], which together generate eight records per day, 2080 records would be generated per year for a plant that operates five days a week, 52 weeks a year.[9] If inspections occur only once every three years, there would be over 6240 records for the inspector to examine.

If inspections occur every five or six years, as planned by FDA during the early years of HACCP implementation, inspectors will face the impossible task of examining up to 12,500 records during a 40 hour inspection visit[10] -- a visit that also includes HACCP plan approval and a traditional plant inspection. If FDA attempts to circumvent this problem by examining a small percentage of records, the agency will undermine the effectiveness of the program's enforcement.

High risk processors are likely to have a higher number of CCPs, so the number of records per year will be even higher. If a processing plant had nine critical control points and three sanitation points, it would generate 6240 records over the two years between FDA inspections.

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[7] The National Advisory Committee on Microbiological Criteria for Foods, "The Role of Regulatory Agencies and Industry in HACCP," adopted June 17, 1993.

[8] FDA estimates the number of CCPs will range from two to twelve per product. 59 Fed. Reg. 19, 4155 (1994) (to be codified at C.F.R. pts. 123 and 1240) (proposed January 28, 1994) (hereafter 59 Fed. Reg. 19) Based on discussions with FDA staff, we believe that the average plant will generate approximately eight records per day, including both sanitation records and critical control point records.

[9] Some plants operate only eight months per year. These plants would generate at least 1400 records per year, assuming they operate 5 days a week during that time and generate eight records per day.

[10] FDA inspectors would have less than 12 seconds to review each record, if they did nothing else during the inspection visit.

FDA is not realistically estimating the inspection force it needs to implement HACCP

The agency has not assessed its future needs for seafood inspection under HACCP realistically. Following HACCP implementation, FDA's inspection staff cannot approve industry plans in a timely fashion. Also, records review will increase the time needed for future inspections even after the initial HACCP approval is completed. Yet the agency claims that it does not need any additional inspection resources. In making this prediction, they are implicitly accepting that inspections will be less frequent in the future.

Without increasing FDA's inspection resources, consumers will continue to find contaminated seafood in the marketplace for many years to come. If the program fails to provide safer seafood products for consumers, this will influence HACCP's acceptability for use on other foods. Additional inspection resources are critical to assure public confidence in HACCP as a tool to assure food safety.

FDA needs stronger regulatory and enforcement authority to ensure that its programs prevent food-borne illness

Mandatory HACCP can only work effectively to improve food safety if it is used as one component within a larger regulatory framework. For seafood, this framework must:

* Extend from the water to the table in order to capture the multitude of potential hazards.

* Include frequent, unannounced inspections by federal regulators to ensure that the plan is being implemented properly.

* Give regulators effective enforcement tools so they can take prompt action against processors that violate their HACCP plans and send contaminated food into the market.

* Mandate that processors provide end-product samples to prove that their HACCP plan actually works to minimize seafood hazards.

FDA's proposal lacks many of these features. The agency needs additional inspection and oversight authority in the following areas to accomplish its mission.

1. Significantly enhanced inspection resources.

FDA's inspection force for seafood must be tripled in size to provide inspections with a minimally appropriate frequency. Current inspection resources can only achieve a 1-to-3 year frequency for in-plant inspections. Under the current proposal, the frequency likely will be stretched to 2-to-6 years for the initial years of HACCP implementation. Tripling the inspection force, assuming this would triple the frequency of inspection, would result in an rate of inspection that is still only barely adequate: three months to once a year normally and 9 months to 2 years during HACCP implementation.

2. Stronger enforcement authority for FDA.

Even a perfect HACCP system will not work unless FDA is given greatly improved enforcement capabilities. At a minimum, FDA needs the authority to:

* Require all operating seafood processors to register with FDA.

* Order the closure of processing plants that are violating FDA's rules, such as the requirement to implement mandatory HACCP.

* Immediately embargo suspected adulterated food products while the agency's investigation is ongoing.

* Review all necessary records and take photographs during plant inspections.

* Order the recall of contaminated food once it has left the processing plant.

* Issue subpoenas to facilitate the agency's collection of documents and testimony from possible violators of the Food, Drug and Cosmetic Act or its regulations.

* Enforce civil penalties or publish the name of violators.

FDA recognizes the inadequacy of its existing authority. In a March 1993 memo from Commissioner Kessler to Secretary Donna Shalala, the Commissioner included many of these elements on his

list of additional statutory authorities that he needs to ensure safe food handling and preparation.[11]

FDA needs significantly strengthened enforcement authority to assure that contaminated seafood can be removed from the market. The Administration should propose legislation to provide FDA with adequate capability to enforce a HACCP program.

3. *Enhanced tolerance-setting and additional resources for sampling to assure the safety of the seafood supply.*

Despite the agency's claim that it has authority to set adequate standards for seafood and to conduct sampling to determine the safety of the seafood supply, the agency has failed to set such standards or carry out the sampling needed to enforce them.[12] As a result, seafood coming to the market is often contaminated with chemical pollutants, including pesticide residues and heavy metals, natural toxins and microbial contaminants. Without more protective standards and an improved sampling program, FDA's existing program can do little to prevent contaminated seafood products from reaching the market.

Tolerances. FDA has only one legally binding tolerance for chemicals found in seafood, which regulates the amount of polychlorinated biphenyls (PCBs) found in fish. FDA also published sixteen informal "action levels," designed to inform the industry of the level of contamination the FDA will accept. These action levels do not have the force of law, are set without public notice or opportunity to comment, and cannot be challenged by consumers, even if they are wholly inadequate. The agency must set legal enforceable limits to protect consumer from the toxic chemicals, natural toxins and microbial contaminates found in seafood.

In *Seafood Safety*, the National Academy of Sciences analyzed the agency's standard setting procedures for PCBs and methylmercury, and in each case found that the standards were not fully protective of many consumers, such as pregnant woman and children. In the case of methylmercury, the NAS recommended that for tuna products intended for consumption by babies and young

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[11] Memorandum cited in Congressional Research Service, "The Safety of Imported Foods," September 17, 1993. FDA confirmed the existence and substance of the memo in discussions with Public Voice.

See, also, Kusserow, Richard P., "FDA Food Safety Inspection," Report of the Department of Health and Human Services Office of the Inspector General, August 1991.

[12] Seafood Safety, p. 240.

children, "much lower levels [than FDA's permissible level] of mercury should be maintained."[13] The Academy specifically criticized the way FDA's procedures allowed economic interests to serve as a counterbalance to public health concerns.[14]

Recently, the Clinton administration introduced legislation that mandates setting pesticide tolerances using the same standard that is applied to food additives. In addition, special provisions were added to address consumers' concerns that the sensitivities of at least one special subgroup -- children -- received adequate consideration. The Administration should extend these protections to setting tolerances for seafood.

Sampling. Tissue sampling is critical for identifying microbial contamination and it is the only method available to disclose chemical contaminants in seafood. Yet the agency takes only a minute number of seafood samples. For example, when the National Academy of Sciences collected data for its report, the Academy found that of the 3.8 billion pounds of seafood consumed in the United States in 1989, FDA took a total of only 7,652 samples, including both domestic and imported products. This represents one sample for every 250 tons of seafood consumed that year.

The most recent baseline survey of chemical contaminants in seafood was conducted in the 1970's. Because of changes in environmental conditions, this survey no longer accurately reflects the presence of chemical contaminants in seafood.

At an FDA-sponsored conference on chemical contaminants[15] in seafood, John Jones, Ph.D., Pesticides and Chemical Contaminants Strategic Manager for the Center for Food Safety and Applied Nutrition reported the agency's conclusions that chemical contaminants did not represent a significant health threat for consumers. In the same presentation, however, Dr Jones reported the following findings from FDA limited surveillance sampling: For tuna, the incidence of DDC (a DDT byproduct) and mercury was high and lead levels were "too high," and a 100% incidence of cadmium; for swordfish and shark, FDA found violation rates of 25% for mercury.

Without conducting statistically valid surveys on a periodic basis to determine the extent and source of seafood

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[13] Seafood Safety, p. 329.

[14] Seafood Safety, p. 190.

[15] FDA Conference on Chemical Contaminants, Washington, D.C., April 21 & 22, 1993.

contamination, the agency cannot determine whether these findings are representative of all seafood entering commercial channels.

The agency must seek adequate funding to provide for periodic statistically-valid sampling that reflects the amount and variety of seafood consumed in this country and the pervasiveness of seafood contamination. A baseline study should be conducted initially of all commercial fisheries. Later, sampling could be targeted to problem fisheries, thereby reducing the expense of testing in later years.

FDA should not be given additional food safety responsibilities until it has the needed resources and authority.

Vice President Gore identified critical inconsistencies in federal oversight of food safety. He recognized the disparate resources and lack of uniformity effect the safety of food products, like meat, poultry and seafood that represent similar risks. Federal food safety programs designed at the beginning of the century must be modernized, so they address the human health risks in the food supply.

Primary federal food safety responsibilities are divided between the United States Departments of Agriculture and Health and Human Services. FDA, under HHS, is charged with ensuring the safety of nearly all foods, with the exception of meat, poultry and eggs. USDA, through its Food Safety and Inspection Service (FSIS), is responsible for meat and poultry. The mission of both agencies is to ensure that the food consumers receive is safe and wholesome.

Various other agencies have responsibilities for aspects of food safety as well. For example, the Centers for Disease Control and Prevention, also under HHS, investigates food-borne illnesses. USDA's Agricultural Marketing Service inspects and grades eggs, dairy, fruit, vegetable, meat and poultry products. USDA's Federal Grain Inspection Service inspects the quality of rice, grain and related products, while its Animal and Plant Health Inspection Service runs regulatory programs to protect animals and plants from pests and disease. The Environmental Protection Agency (EPA) is responsible for regulating pesticides and setting pesticide tolerances. The Commerce Department's National Marine Fisheries Service runs a voluntary seafood inspection program. The Customs Service, under the Treasury Department, examines and collects food import samples.

As these many duties demonstrate, ensuring food safety is a complicated endeavor. Not only does it encompass research and inspection, but it must address the entire length of the food

chain -- water feed and soil quality at the earliest stages; processing and retail distribution at the later ones.

Combining food safety functions into one agency could result in significant administrative savings, while at the same time addressing the inconsistencies, overlapping responsibilities and conflicting missions inherent in the existing system for food safety monitoring. This approach is one that is worth further exploration.

Although, as Vice President Gore recognized, the FDA has the type of public health mission that would make it a candidate to assume greater food safety functions, without the enhancements in resources and authority that we have described above, any expansion in FDA's scope of responsibility should not be considered. In addition, the agency's placement in Health and Human Services may actually exacerbate problems with its ability to get adequate funding.

For example, the Clinton Administration's 1995 budget proposal for FDA contains a 43% cut in public funding for FDA's Foods Program from $221 million to $125 million. This public funding is supplemented by $93 million in fictitious user fees, bringing the total budget figure using smoke and mirrors to $221, the same level as the agency received in 1994. As we have demonstrated above, this is taking the agency in exactly the wrong direction and raising questions as to whether the Clinton Administration is trying to starve its top food safety agency.

This year, Public Voice testified before the House Appropriations Committee to urge that the Food and Drug Administration receive an increase for its Foods budget of at least 10% over the FY 1994 budget to address long term deficiencies in the program. In addition to this, the agency should receive an additional $10 million in dedicated funding to conduct training and increased inspections to implement its seafood HACCP regulation.

If the agency is given the increased resources and authority it needs, consumers should see a substantial improvement in the safety of their food, especially seafood products. Eventually, a revamped FDA could be strong candidate for greater responsibility for food safety. Without this help, however, consumer confidence in seafood will continue to decline, and the cost in individual human life and health will remain dear.

Mr. TOWNS. Let me thank both of you for your very fine statements. Let me begin with just some quick kinds of questions that probably could be answered by a yes or no.

I would like to ask both of you, can FDA inspection programs ensure the safety of imported food, Mr. Harman.

Mr. HARMAN. Under the current system, no, it cannot, not with any assurance for the consumer.

Mr. TOWNS. Ms. DeWaal.

Ms. DEWAAL. I would agree with Mr. Harman's assessment.

Mr. TOWNS. Can FDA's inspection program ensure the safety of domestically produced food?

Mr. HARMAN. It cannot assure whether it is safe or whether it is not safe.

Ms. DEWAAL. And it is not currently ensuring it, that is true.

Mr. TOWNS. Does FDA lack sufficient resources to perform its current food safety responsibilities, yes or no?

Mr. HARMAN. Yes.

Ms. DEWAAL. Yes.

Mr. TOWNS. Does FDA have sufficient legislative authority to take enforcement actions against unsafe food and firms that fail to comply with the law, yes or no?

Mr. HARMAN. No.

Ms. DEWAAL. No.

Mr. TOWNS. Should FDA be given additional food safety responsibilities without additional resources and authority, yes or no?

Mr. HARMAN. No.

Ms. DEWAAL. No.

Mr. TOWNS. Let me ask you, Mr. Harman. Does GAO recommend that meat and poultry inspections be removed from USDA because of an inherent conflict of interest in that department?

Mr. HARMAN. Yes, that has been our position, Mr. Chairman, for a number of years.

Mr. TOWNS. You stated that FDA needs additional enforcement authority. Last September, the subcommittee asked GAO to evaluate the effectiveness of FDA's enforcement actions. What is the status of that evaluation?

Mr. HARMAN. I knew you were going to ask that question, Mr. Chairman. I wish I had a good answer, but right now we are in the process of staffing that work. We are finishing up two other jobs that we were doing for the subcommittee and as soon as we are—they will be out this month, and then we will be starting that work.

Mr. TOWNS. It is going to start this month?

Mr. HARMAN. Yes.

Mr. TOWNS. OK, next month?

Mr. HARMAN. Probably next month.

Mr. HARMAN. What I mean is Ed is going to start next month.

Mr. TOWNS. That is encouraging.

Mr. ZADJURA. For you maybe.

Mr. TOWNS. Ms. DeWaal, according to your analysis, does FDA have sufficient resources to implement its HACCP program, yes or no?

Ms. DEWAAL. No. It lacks critically needed inspection resources and critically needed enforcement authority.

Mr. TOWNS. If FDA does not get additional resources to implement HACCP, would the number of inspections decline?

Ms. DEWAAL. Yes. We anticipate that the number of inspections will decline by about 50 percent. They are currently totally inadequate, and it would decline to once every 2 years for high-risk processors and once every 5 to 6 years for your average processor. That is nowhere near adequate.

Mr. TOWNS. What impact would fewer FDA inspections have on the public health?

Ms. DEWAAL. Well consumers don't have confidence right now in the safety of the seafood supply, and I think there will be even more questions in the future. Certainly the processors who are doing the right things now are going to do better under HACCP. We think that good processors will implement a good program, but the processors who aren't registered with FDA currently, and there are many of those, or ones that aren't operating under HACCP will have food safety problems coming out of those companies.

Mr. TOWNS. Thank you. USDA now requires a safe handling and cooking label on raw meat and poultry. Does FDA need to require a similar label on other raw animal products such as raw oysters?

Ms. DEWAAL. Yes. Raw oysters are a particular concern because they are consumed raw, they aren't even subject to any cooking by consumers, and, Mr. Chairman, there is a very personal human cost to the fact that they haven't put these labels on raw oysters.

We have a woman here who flew up from Florida yesterday, Mrs. Vicki Peal. Her 80-year-old father died after consuming raw oysters at a restaurant, and she came up here this morning to attend a press conference to join our call for this label because she believes if it had been in place her father would not have died.

Mr. SCHIFF. Mr. Chairman, would you yield on that?

Mr. TOWNS. In fact, I will yield to you for your 5 minutes.

Mr. SCHIFF. I will take it, then. I will follow up right there. Ms. DeWaal, maybe I should have caught this earlier, what would the label say?

Ms. DEWAAL. The label, which Public Voice asked FDA to mandate in August 1991, "Warning: Eating raw or partially cooked shellfish can cause serious illness and even death. Persons at greatest risk are those with the following conditions: Alcoholism, liver disease, cancer, diabetes, kidney disease, steroid dependency, AIDS, chronic intestinal disease, achlorhydria, hemochromatosis/hemosiderosis." It is targeted to the groups that are at high risk, but let me just talk for 1 second about the risk involved here.

People with these conditions who consume raw oysters that have this common marine bacteria, they have a 50 percent chance of dying. It is a very serious illness. For most of us, we will consume raw shellfish without much of a problem, though we may have a mild stomach flu, but for people in these high-risk categories, it can mean the difference between life and death.

Mr. SCHIFF. How would you get that message across to people ordering raw shellfish in restaurants or would you expect the restaurant to communicate that in some way when they purchase the product?

Ms. DEWAAL. We have asked that point-of-purchase signs be used where seafood is picked up, such as at a deli counter or at

a restaurant. Some States have implemented the use of table tents, and also you can——

Mr. SCHIFF. I am sorry, such as what?

Ms. DEWAAL. Table tents. This is a table tent, but the way they are used in restaurants that would have the warning, and also some States have asked that they be put right on the menus.

Mr. SCHIFF. I have one question of both witnesses. Both witnesses have said that before there should be a consolidation under the FDA, or for that matter possibly even the creation of a new agency, there needs to be more resources and legislative improvement.

Now, resources we understand. I mean, coming up with the dollars is not always that easy, but certainly we hear your message up here. Could you give a couple examples, though, of what legislative changes ought to be made to improve the ability of the FDA even now to do their job to ensure a safe food supply?

Mr. HARMAN. Well, first of all, let me just make a comment about resources. Under the current system, I don't know if there is enough resources or there is not enough resources in the total food safety system. What we have is a lot of duplication among agencies like USDA and FDA, and there is a lot of inconsistency between the resources we are applying to meat and poultry, and there is a question about how effective that application of resources is as well as the relatively minor amount of resources being applied to all other food products. So until you reengineer, reinvent, so to speak, the system, it could very well be you have enough, "resources," money; it may not be the right people, but you might have the money. We don't know that yet.

In terms of legislation we think are needed right now, one is we think there needs to be legislation that gives them authority to impose civil penalties that they don't have right now. We think there needs to be legislation that allows them to prevent the entry into the food system of contaminated food before it gets in the system, not after, similar to what USDA has, as well as access, better access to the production and distribution records of companies, and that is particularly important as we implement HACCP because it becomes—the role changes with HACCP to be more identifying of those points where there is weaknesses, and those records are going to become very important then.

I don't know if Ed has any more to add, but——

Mr. ZADJURA. They probably also need either a registration or a notification requirement because, unlike USDA, you don't even have to tell FDA that you are in business. Presumption of interstate commerce right now, although my guess is most firms comply when challenged by FDA, they have had to go into court on occasion and prove that a firm is engaged in interstate commerce and therefore under its jurisdiction.

USDA, on the other hand, every meat and poultry processing plant is presumed to be in interstate commerce. They need the authority to approve or ban equipment or processes that are known to contribute to contamination. I think that would generally sum up——

Mr. SCHIFF. Mr. Chairman, I ask for unanimous consent for another minute because Ms. DeWaal didn't have a chance to answer the same question. Ms. DeWaal.

Ms. DEWAAL. I will join with my colleagues from GAO in many of these things. If FDA goes into a processing plant and sees contaminated food, they can't even seize that food. They have to go to court and come back with an order for seizure. Their enforcement authority is very, very limited, and we would ask for embargo authority, seizure authority, and registration authority, all of those things are just critical to the agency's ability to do its job.

Mr. SCHIFF. And that is true now?

Mr. HARMAN. That is true now, and I would add that these things were laid out fairly effectively in a Commissioner's memorandum to the Secretary of HHS in March 1993, so they are recognized at FDA also.

Mr. SCHIFF. Well, let me just conclude with this, I would invite, particularly the General Accounting Office but obviously any other group that feels that we can improve what the FDA can do today on behalf of the American public through legislative changes perhaps as far as you think it is appropriate to go in your agency, I would welcome your drafting the legislation.

Mr. HARMAN. We would be pleased to do that.

Mr. SCHIFF. Submit it to me and the chairman and we will distribute it to the other Members and we will take a look at it and see if we can move it along here. There is no reason not to do something because we can't do everything.

I yield back, Mr. Chairman.

Mr. TOWNS. At this time I yield to Congressman Payne.

Mr. PAYNE. Thank you very much.

That was sort of the question I was going to ask, do you think that, both of you, that the HACCP program as proposed by FDA currently is good enough and will it meet the current need for the existing food supply, and I wonder whether you think that what is being proposed goes far enough?

Mr. HARMAN. Let me just say before I let Ed say a few words here is that we are totally in support of the concept of HACCP, and the risk-based system that it implies, but with that, let me have Ed talk about the current proposal that FDA has.

Mr. ZADJURA. Certainly as John said we, in all our testimonies and reports going back years have supported the concept of HACCP because of its presumption to prevent hazards before they get into the food supply rather than trying to catch them later.

The HACCP program for seafood that FDA has recently put into effect is a cooperative agreement that the industry worked on with them, and as such it is a monumental step in the right way because, as Ms. DeWaal said, FDA inspects seafood processing facilities at a very low rate, but it is a compromise program.

Recently at a conference I heard the director of the seafood program assure a questioner in the audience that if processing plants could meet the National Marine Fisheries' voluntary program, that the plants pay to get in, they would have no problem meeting FDA's, because the voluntary paid program, which is primarily a grading program, was stricter. So I think that tells you we could probably do a better job because FDA does not have the authority

to mandate this type of program; they do not have the access to records. It was a compromise. Now it is a good one and it is a step in the right direction, and it is very positive, but it will not take care of all the problems.

Ms. DEWAAL. We have spent many months doing a very thorough review of FDA's proposal. It lacks a critical feature of HACCP as it was designed by the national advisory committee on the microbiological contamination of food, and that is the verification requirement. That is the requirement that shows that HACCP is really working to make a product cleaner and safer.

FDA has omitted from their plan the requirement that companies do end-product sampling to show that the product coming out at the end of a HACCP line is cleaner than it was before HACCP was implemented. This is a critical feature of HACCP and one that we are urging that the agency put back into the proposal.

It also doesn't even require prior approval of the HACCP plans by the agency. It may be 5 years before the agency even arrives at a plant to check their HACCP plan, and that is not adequate. So there are some critical weaknesses.

Mr. PAYNE. Thank you. Do you know whether any States currently require warning labels to be placed on raw seafood products?

Ms. DEWAAL. Yes. California and Louisiana about 2 years ago first instituted mandatory labeling. Florida just this year has finally instituted mandatory labeling after they have had a number of deaths in that State.

Mr. PAYNE. And these include restaurants and so forth?

Ms. DEWAAL. Yes.

Mr. PAYNE. I am just curious if anyone would know in the consumption behavior, most, say, for example, oysters which seems to be the serious problem, is most of it consumed at a restaurant or is it done through the canning process and people buy the product and take it home? Is there any way to know?

Ms. DEWAAL. Much seafood generally is consumed at restaurants, so I would suspect that that is also the case with raw oysters, but you can go to your local supermarkets and fish stores and pick up jars of shucked raw oysters, also they come in containers like this and labels are put on them for pricing purposes, so, you know, we have an industry like meat and poultry which has similar packaging issues, they have managed to institute labels. I think the restaurants—many of the States, and Florida is one of them, have tackled the issue of restaurants, and I think they could do it effectively as well.

Mr. PAYNE. I just wondered, it looks like my time has almost expired, but let me ask this last question, unanimous consent for 1 minute as my colleague did.

Mr. TOWNS. Without objection.

Mr. PAYNE. All right, so we have 6-minute turns.

Is there any way that either one of you know how the industry can improve the quality of oysters or at some point would you even recommend that it be a restricted product?

Ms. DEWAAL. One—the oysters that are harvested during a particular time of year are the ones that we are particularly concerned about, they have to come out of warm marine waters, and the problem is particularly common in the gulf coast States, and one clear

thing they could do is cook the products, but there is a lot of resistance to doing that.

They could restrict harvesting during those summer months; they could mandate that any harvested products were cooked. We think labeling is a low-impact approach to achieve the same result because the impact is really for these high-risk groups. Those are where the incidence of fatalities, the deaths have really occurred.

Mr. PAYNE. Thank you very much. I think that a majority of people are unaware, believe me, and I think that labeling is, I agree, the answer. I don't know who would eat raw oysters knowing the risks involved. That is like standing out in the middle of a highway.

So I would thank you very much, Mr. Chairman.

Mr. TOWNS. Thank you. At this time I yield to Mr. Mica.

Mr. MICA. Mr. Harman, I think the only thing that could probably be worse than me eating contaminated shellfish would be for you to suggest using EPA as a model for a consolidated agency to oversee food safety. I absolutely shudder at the thought. I serve on the other subcommittee that oversees EPA, and I can assure you, sir, that that is not a model to look after.

I have a couple of concerns about a consolidation proposal. First of all, from the National Performance Review and suggestions I guess by the Vice President, I think he said that duplication and inspection may be killing us because we have got, what is it, 21 agencies involved in inspection and not doing a very good job. I was trying to get a handle on the dollar figure and personnel figure of how many people are involved in those 21 agencies that are involved in this process.

Mr. HARMAN. Well, I guess first of all, let me say also that we experienced the same comment as we processed our testimony through our office about EPA. We try to do a little tweaking, it said while operating much like EPA. We are looking for structure there.

Mr. ZADJURA. We meant independent, not their mode of operation.

I believe the actual figure, Mr. Mica, is 12 agencies, because they took it from a GAO report, and it is about $1 billion a year. Most of that money is concentrated in two agencies—FSIS within USDA which spends about $650 million a year. The bulk of the rest of it is in FDA. There is some in, as we said, National Marine Fisheries, AMS, the agriculture marketing service within USDA, parts of EPA that deal with food, pesticide, setting tolerances on food products and stuff like that.

As far as staff levels go, USDA has about 11,000 staff years to oversee, about 6,100 slaughter and processing plants for both meat and poultry. FDA, on the other hand, has about 8,900 staff years to oversee all of their food, drug and medical devices responsibilities. The bulk of that goes to other than food. About 2,600 staff years are used by FDA to oversee more than 50,000 firms under their jurisdiction in the United States, and about 1.2 million shipments of imported food that is under their jurisdiction.

One of the reasons for the difference in resources is when you look back at their authority which is why we keep saying needs to be made uniform and consistent, by law, USDA must inspect every single carcass and every single poultry slaughtered, and for poultry

alone that is over 6 billion birds, so the vast bulk of their resources, about 77 percent, go to looking at every single carcass because they have this preapproval requirement that they put a stamp on it before it goes out.

FDA, on the other hand, sort of chases the fox after it has got out of the hen house, and isn't required to inspect plants on a daily basis, or even an annual basis. As a matter of fact, we recently found that their inspections are slipping from about once in every 3 to 5 years in 1992 to about once in every 8 years now on average, which you can tell they don't show up very often.

Mr. MICA. Let me ask a question. And I am concerned with your comments, Ms. DeWaal, about I guess you quoted someone about chasing the horse after they have left the barn which seems to be FDA's modus operandi. It may be impossible to continue inspecting everything that is imported.

I noticed in the statistics we have gone from half a million products to over 1,117,000 products now that are imported. If we can't use the touch, smell, and taste method, or whatever you are using, you can use either standards or technology. What is the progress with increased emphasis on technology for inspection and then standards?

I am also concerned, too, that the standards, just say for shellfish in Florida or a national standard, we have known there has been a problem, we have known there has been a problem, people are dying, and yet nothing is done about it, so you either have standards or you have some technology to try to cover the large area that you are responsible for.

Mr. HARMAN. Well, there is no doubt that the need right now is for standards and for technology to test for microbial contamination, whether it is on fruits and vegetables or on seafood or on meat and poultry, and we have known that for some 15 years, that that is the major risk.

Progress has been, I guess it would be safe to say, slow at best, and right now, and I am not too familiar with the seafood situation, I will let you talk about that, but the meat and poultry particularly, there now are efforts, and industry is way ahead right now, from our judgment, of USDA on meat and poultry on developing microbial testing methods. They are all over the board in terms of what they are doing, but USDA is basically doing a lot of surveys to try to come up with standards.

Our position is you don't need to go to standards right away. You need to start—thinking of the HACCP system, the primary responsibility for the safety and quality of food in this country rests with the producer and with the processors. We are here, the government is here because that hasn't always happened in the past, and so the system that we would call for is a HACCP-type system that you would identify those points where you have the highest risk, and the government comes in and makes sure and agrees that those are the points and makes sure that you are doing your job in monitoring those conditions, so meat and poultry, the standards aren't there.

We think they could do some work to get some guidelines out and start working with industry to identify areas and start communicating with other plants on where there is problems. There is a

lot of things that can happen short of standards, and particularly meat and poultry, but it is a problem, it needs to be developed.

Mr. TOWNS. The gentleman's time has expired.

Mr. MICA. Thank you.

Mr. TOWNS. Thank you very much. Let me thank all of the witnesses for your testimony.

Let me just, as you leave the table, let me sort of clear up one thing. I heard the number $650 million, and we have been told it is more like $1 billion, so what——

Mr. ZADJURA. It is $1 billion, Mr. Chairman. The $650 million is solely FSIS for meat and poultry inspection. The $1 billion is a number that we calculated about 2 years ago by looking at the 12 agencies involved and trying to pull out their food work.

Can I check this before I—we can give you the break out by agency staff years. It is about 2 years old, but it was about $1 billion. Like I said, $600 to $650 million was primarily FSIS for meat and poultry, then there is a portion that is FDA, a portion that some other small agencies are involved, and the figure in 1992 was approximately $1 billion, and we will supply it to you.

Mr. TOWNS. Thank you very much. Thank all of you for your testimony.

[The information referred to follows:]

Fiscal Year 1993 Food Safety Funding and Staffing

The table below shows that the government spends over $1 billion annually on food safety activities.

Department/Agency	Dollars (in mils.)	Staff years (fte's)
USDA:		
FSIS	$558.0	10,750
AMS	118.7	2,193
FGIS	.4	4
ARS	36.0	400
APHIS	266.6	3,991
HHS:		
FDA	205.0	2,695
CDC	2.9	25
EPA	.8	21
NMFS (note a)	14.0	251
Federal Trade Comm.	(note b)	(note b)
TREASURY: U.S.Customs & ATF	(note b)	(note b)
TOTALS	$1,202.4	20,330

Notes:

a This funding is from user fees for the voluntary seafood inspection program. Other agencies, such as, FSIS and AMS may also have some funding from user fees.

b In prior reports we did not obtain data for the Federal Trade Commission and Treasury's U.S. Customs Service and Bureau of Alcohol, Tobacco and Firearms and have not attempted to obtain the data for fiscal year 1993.

Source: GAO presentation of agency supplied data.

Mr. TOWNS. I would like to call our second panel, Dr. Peggy Foegeding, Dr. John Guzewich, and Dr. Gary Hlady.

It is the custom of the subcommittee to swear in our witnesses. Will you please stand and raise your right hand.

[Witnesses sworn.]

Mr. TOWNS. Let the record show that the witnesses answered in the affirmative.

Let me thank you very, very much for coming and as you probably heard, your entire statement will be included in the record. Please summarize within 5 minutes to allow the members of the panel to raise questions with you. When the red light comes on, we would like you to conclude. So why don't we begin with Dr. Foegeding.

STATEMENT OF PEGGY M. FOEGEDING, Ph.D., PROFESSOR, FOOD SCIENCE AND MICROBIOLOGY, NORTH CAROLINA STATE UNIVERSITY

Dr. FOEGEDING. Thank you, Mr. Chairman and members of the subcommittee. I am pleased to be here today to address food safety issues with you. I am Peggy Foegeding, I am a professor of food science and microbiology at North Carolina State University. I teach and study food safety microbiology and the effect of food processing and handling on the safety of foods.

I am here today on behalf of CAST, the Council for Agricultural Science and Technology. CAST is devoted to advancing the understanding and use of food and agricultural science in the public interest. Recently, along with my colleague Dr. Tanya Roberts from the Economic Research Service, I have been cochairing a task force which was convened by CAST to prepare a report entitled "Foodborne Pathogens: Risks and Consequences." This report will be available in June. I would respectfully request that the record be held open for the summary of this report when it is available next month.

Mr. TOWNS. Without objection.

[The information can be found in appendix 5.]

Dr. FOEGEDING. My primary message is that the food supply in the United States is very safe overall, yet improvements could be made now and in the future.

To capitalize on the current opportunity requires an honest discussion and understanding that risk minimization should be the goal and zero risk is not possible. The main food safety concern in the United States is harmful microorganisms and their toxins which may be present in foods and cause acute or chronic human illness. These causes an estimated 6.5 million to 33 million cases of foodborne illness annually in the United States and may result in as many as 200 to 9,000 deaths annually in the United States.

Foods of animal origin are most often identified as the causes of foodborne disease, yet other foods are also involved including those of plant origin, and I would refer you to table 1 in the written statement.

The principles of food safety and control are largely the same regardless of food commodity. However, one cannot ignore the important differences which are commodity specific or specific to the particular process which the food undergoes.

For imported and domestic foods, the safety will depend upon the source and quality of the raw components as well as on how the food is processed, handled, distributed, stored, and prepared. There is reason to be concerned that the source of imported foods may increase the risk in certain situations, and I have provided some examples in my written statement.

The application of hazard analysis critical control point, or HACCP, systems should improve safety if applied appropriately. We are the beneficiaries of research information that has been generated largely through research which has been sponsored by the Food and Drug Administration, the U.S. Department of Agriculture, land-grant universities, other agencies or institutions, as well as food companies.

The scientific knowledge generated from the research has provided the opportunity to apply modern concepts such as quantitative risk assessment to decisionmaking and preventive strategies. I believe we presently are poised to make changes which will have a lasting and positive impact on food safety. Current and new opportunities are detailed in table 2 in the written statement.

It is my opinion that the existing Federal food safety system has helped us in that our food supply is generally very safe. For the most part it is designed to prevent, control, eliminate, or reduce primary risks of foodborne illness at the processing level. But it is not really targeted at food handling and procurement that is beyond the processing level at either the production side or at the retail side after it leaves the processing facility.

In my opinion, the Federal food safety system should have a consistent and scientifically sound philosophy which has public health as its primary focus. It should be developed using sound scientific information and guided by quantitative risk assessment. The system should acknowledge that risk cannot be eliminated but must be minimized.

Thank you very much.

Mr. TOWNS. Thank you for your testimony.

[The prepared statement of Dr. Foegeding follows:]

Statement of

PEGGY M. FOEGEDING, Ph.D.
PROFESSOR
DEPARTMENT OF FOOD SCIENCE
and
DEPARTMENT OF MICROBIOLOGY
NORTH CAROLINA STATE UNIVERSITY

before the
HOUSE COMMITTEE ON GOVERNMENT OPERATIONS
SUBCOMMITTEE ON HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS

May 25, 1994

Mr. Chairman and Members of the Subcommittee, I am pleased to be here today on behalf of the Council for Agricultural Science and Technology (CAST) to address food safety issues. I am Peggy Matthews Foegeding, professor of food science and microbiology at North Carolina State University. I have been on the faculty at NC State University since 1982 as a teacher and researcher. I teach and study food safety microbiology and the effects of food processing, handling and storage on food safety. Presently, I am the chair of the USDA National Research Initiative Panel on Food Safety which makes recommendations on competitive research funding on this topic.

Recently, I have been the co-chair, with Dr. Tanya Roberts (Economic Research Service, U.S. Department of Agriculture) of a Task Force involving 13 additional scientists, physicians and individuals interested in food safety, which was convened by the Council for Agricultural Science and Technology.. We are preparing a report entitled "Foodborne Pathogens: Risks and Consequences" which is in the final stages of review and should be available in June. CAST is a coalition of 30 scientific societies devoted to advancing the understanding and use of food and agricultural science and technology in the public interest.

I have submitted a written statement and request it be inserted into the record. I also request that the record be held open for the inclusion of the interpretive summary of the aforementioned CAST report when it is available.

I have been asked to address food safety and the federal food safety system. Mr. Chairman, you detailed six specific issues related to food safety which you wish me to address.

THE PRIMARY MESSAGE with which I wish to leave you is that the food supply in the U.S. is very safe overall yet improvements could be made now and in the future. The time is ripe because of the current public interest, regulatory opportunities, and scientific information and

tools available. To capitalize on this opportunity, however, requires an honest discussion and understanding that risk minimization should be the goal and zero risk is not attainable.

As a result of the deliberations of the CAST Task Force and my own research and review of the literature, I believe the following points are important to your efforts.

1. It is clear that a comprehensive system of assessing risk of human illness from hazards in the food supply has yet to be created. The main food safety concern in the U.S., both in terms of numbers and severity of cases as well as economic impact, is harmful microorganisms and their toxins which may be present in foods and may cause acute or chronic human illness. Although the current foodborne-disease burden of the United States is not known with accuracy, cases are likely to range from 6.5 million to 33 million annually in the U.S. and deaths from 200 to 9000 annually.

2. Protein foods of animal origin are most often identified as the causes of foodborne-disease outbreaks which are reported to the Centers for Disease Control and Prevention; yet a wide variety of foods, including those of plant origin, also may contain low levels of harmful microorganisms or pathogens. Table 1 details selected hazardous microorganisms associated with various foods. [References for Table 1 will be provided in the CAST report. For information on the prevalence of mycotoxin-producing molds see the 1989 CAST report.]

3. From a purely microbiological standpoint, there are more commonalities about food safety microbiology and mechanisms to control hazardous organisms in various types of foods than there are differences. That is, the principles of food safety and control are largely the same regardless of food commodity. However, one cannot ignore the important differences which are a consequence of the specific food or food ingredients or process. These are illustrated in the following table.

Differences in microbiology according to the food or process	Example
likelihood of a particular hazard (presence of a particular organism) according to the particular food	Pathogenic *Yersinia enterocolitica* is associated with swine more frequently than with other animals or plant foods.
likelihood an organism would be a concern according to the particular process	The potential for *Staphylococcus aureus* growth and toxin production in foods preserved by reducing the water activity would be a primary safety concern.

processing scenarios may influence the practicality of applying selected tests to validate safety	Foods preserved to achieve a long shelf life (example: refrigerated puddings) could be held in a warehouse while extensive, time consuming microbiological validation of safety is done while this is not practical for highly perishable foods (example: fresh fish).

4. Pathogens enter the food chain at different points from the farm to the kitchen table. Methods of entry include presence in/on the raw food or ingredients, environmental contamination (including the food processing environment), and food handler contamination. Methods to prevent or to control pathogens differ according to the point of entry and type of hazardous organism or toxin. The control methods may include the following or other approaches or treatments.

- Monitoring feed and food ingredients to avoid use of contaminated materials,
- practicing good cleaning and sanitation to reduce the contamination from the food processing environment,
- refrigerating to prevent or minimize growth of or toxin production by harmful organisms,
- cooking or pasteurizing to reduce levels of organisms which are present or to inactivate those toxins which are heat sensitive,
- adding appropriate preservatives to prevent or slow growth and toxin production,
- dehydrating to prevent growth,
- fermenting to prevent growth, or
- irradiating to kill hazardous organisms which may be present.

Many pathogens and toxins differ in their sensitivity to control methods. Some pathogens or toxins are resistant to selected controls which are highly effective for other pathogens or toxins. No one method will eliminate all pathogens and microbial toxins from the food chain. Effective strategies trequently encompass several control steps. Since these controls are critical lines of defense to improve the safety of foods it is important that they be carefully applied and monitored to assure they are properly administered. This is one key concept in hazard analysis critical control point systems.

5. The current opportunities for improving food safety are grounded in the scientific knowledge which we have relative to, for example, hazardous organisms and their toxins, food handling and processing methods for enhanced food safety, improved methods available for epidemiological studies which trace organisms through the food chain to the consumer, and improved methods available for detection of organisms in foods. The scientific knowledge has provided the opportunity to apply modern concepts such as quantitative risk assessment, and new methods of information management and dissemination, to decision-making and preventative strategies.

6. Factors which contribute to the increased concern about foodborne diseases include

- introduction of new food products with reduced levels of microbial barriers (more "fresh-like"),
- proliferation of ready-to-eat (not requiring a final cooking step) refrigerated convenience foods with an extended shelf life (allowing time for growth of those pathogens which may grow in the product at refrigeration temperatures),
- large, sophisticated, distribution channels (which may allow time for growth and opportunity for cross contamination);
- increased potential for mishandling during final preparation and storage of prepared foods; and
- consumer preference for undercooked or uncooked foods of animal origin (lightly cooked eggs, rare meat, raw oysters).

Many of the foods which cause confusion and concern are available because these are the types of foods the consumers are demanding. With the diversity of foods available and globalization of our food supply, there is more likelihood for confusion about appropriate safe-handling procedures prior to consumption on the part of food preparers and consumers.

7. Imported foods may be less, more, or equal in safety to domestic foods. As for domestic foods, the safety will depend upon the source and quality of the raw components as well as how the food is processed, handled, distributed, stored and prepared. There is reason to be concerned that the source of imported foods may increase the risk in certain situations, such as the increased likelihood of *Vibrio cholerae* in seafood originating in South or Central America, or imported fruits and vegetables which have been washed with what is considered potable water in the country of origin but is not potable by U.S. standards.

8. The application of hazard analysis critical control point (HACCP) systems should reduce the likelihood of foodborne illness. The potential of this method is exciting because it is proactive, responsive, and grounded in good scientific information. The efficacy of an HACCP system depends upon the rigor and care with which it is applied including comprehensive identification of all hazards. It is important that HACCP systems be implemented similarly for all foods which pose a food safety risk if we are to enjoy fully the improved safety HACCP can bring.

You asked that I address the extent to which the nation is prepared to handle emerging infectious diseases.

I believe we presently are poised to make changes which will have a lasting and positive impact on food safety; some changes have occurred or been proposed recently. These opportunities are an indication that the public is the beneficiary of research knowledge primarily provided through the State Agricultural Experiment Stations, U.S. Agricultural Research Service, U.S. Department of Agriculture's National Research Initiative in Food Safety, and food industry research support.

New opportunities exist for prevention, reduction, and destruction of pathogens or their toxins in foods. Historically, primary efforts at control have been focused on food processing and food service. New strategies involve these areas, yet also extend control efforts to the farm and to the home. Some of the current and new opportunities are detailed in Table 2.

There is a great deal of excitement for the potential of HACCP and new processing technologies to improve food safety. Undoubtedly, HACCP will be a significant regulatory advance and will improve food safety. I would offer two cautions to the use of HACCP as a regulatory tool, those being the importance of both good design and good implementation.

> First: Regulatory agencies should not mandate HACCP programs which are either (i) too difficult or expensive to implement such that they are not practical, or (ii) which dilute the food safety aspects by inclusion of other regulatory issues. Either case would diminish the positive impact of HACCP in reducing foodborne disease.
>
> Second: The impact of HACCP will only be as good as the implementation. It is possible that HACCP may be implemented unevenly (for example, from product to product or processing location to location) and therefore its potential positive impact will be diminished.

Other opportunities, such as new processing technologies, to improve food safety and reduce foodborne disease in addition to HACCP are available and will continue to present themselves. We must continue generating and applying the new knowledge relative to food safety.

You asked me to address the extent to which the existing Federal food safety system is designed to prevent, control, reduce or eliminate the primary risks of food borne illness.

It is my opinion that the existing Federal food safety system has helped us in that our food supply is generally very safe. However, I believe the current system does not take a "systems approach" to food safety and that is one shortcoming. For the most part, it is designed to prevent, control, eliminate or reduce primary risks of foodborne illness at the processing level, but not prior to processing (at the production level) or after the food leaves the processing facility. Perhaps more importantly, because the existing Federal food safety system involves many agencies (including the Department of Defense, Environmental Protection Agency, Food and Drug Administration, National Marine Fisheries Service, and U.S. Department of Agriculture), I believe the system is confusing in that it does not speak with one voice to the food, agriculture, and allied industries or to the consumers. I believe that if the system were designed to be administered by one agency, it would be more effective because there would be a common philosophy and uniform goals.

Finally, you asked me to address the major components and guiding principles of an optimal Federal food safety system.

In my opinion, the Federal food safety system should have a consistent and scientifically sound philosophy which has public health as its primary focus. The Federal food safety system should be even-handed and have expectations which are consistent for all foods of equal risk and intended for consumption by similarly sensitive populations.

Additionally, the Federal food safety system should consider aspects of food handling which can impact safety from the farm to the consumer. It should be recognized that the optimal system will include multiple approaches and should respond to modern technologies and concepts.

I believe the Federal food safety system must be developed using sound scientific information and guided by quantitative risk assessment, as proposed by the National Academy of Sciences. The system should acknowledge that risk cannot be eliminated but should be minimized to the extent that a knowledgeable public demands. A knowledgeable public would recognize that zero risk is not attainable and that there are economic consequences of risk reduction. Research guides and provides opportunity for quantitative risk assessment. Quantitative risk assessment gives a rational and practical framework - a cost/benefit or pro/con focus - where it is applied, including to regulatory activities. In this way, resources would be managed and allocated where practical and theoretical knowledge indicates they provide the greatest benefit to the public.

It is important to capitalize on the synergism gained from appropriate research, education and implementation relative to food safety knowledge and advancements. It is critical to continue research to generate new knowledge relative to food safety, and to continue educational efforts to disseminate the knowledge so that it can be properly and wisely implemented by policy makers, regulators, producers, processors, food-handlers, public health officials, and consumers. Informed implementation will be enhanced by honest public discussion regarding needs, expectations, and costs.

Table 1. Prevalence of pathogens or potential pathogens in foods

Organism	Food	Percent positive	Reference
Aeromonas hydrophila[a]	Seafood	19–100	Abeyta, 1983, Abeyta et al., 1989, Colburn et al., 1989, Fricker and Tompsett, 1989, Palumbo et al., 1985
	Raw milk	33	Palumbo et al., 1985
	Poultry	16–100	Barnhart et al., 1989, Fricker and Tompsett, 1989, Palumbo et al., 1985, Ternstrom and Molin, 1987
	Red meats	100	Palumbo et al., 1985
	Cooked meats	10	Fricker and Tompsett, 1989
	Pork	6–27	Fricker and Tompsett, 1989, Ternstrom and Molin, 1987
	Beef	11–33	Fricker and Tompsett, 1989; Ternstrom and Molin, 1987
	Produce	95	Callister and Agger, 1987
Aeromonas species[a]	Lamb	59	Marjeed et al., 1989
Anisakid nematodes	Marine and anadromous fish	0–100	Myers, 1979
Bacillus cereus	Pork	4–7	Konuma et al., 1988, Ternstrom and Molin, 1987
	Beef	11–63	Konuma et al., 1988, Ternstrom and Molin, 1987
	Chicken	0–7	Sooltan et al., 1987, Ternstrom and Molin, 1987, Weagant et al., 1988
	Meat additives	39	Konuma et al., 1988
	Raw milk	9	Ahmed et al., 1983
	Pasteurized milk	35	Ahmed et al., 1983
	Dairy products	0–63	Ahmed et al., 1983; Mosso et al., 1989, Rodriguez and Barrett, 1986
	Raw rice	100	Bryan et al., 1981
	Pasta and flour	0	Mosso et al., 1989
	Seafood	1	Abeyta, 1983
Campylobacter (thermophilic)	Pork carcasses	17	Lammerding et al., 1988
	Beef carcasses	23	Lammerding et al., 1988
	Veal carcasses	43	Lammerding et al., 1988
	Turkey carcasses	74	Lammerding et al., 1988
	Chicken carcasses	38	Lammerding et al., 1988
Campylobacter coli	Pork carcasses	13	Bracewell et al., 1985
Campylobacter jejuni	Pork	0–24	Mafu et al., 1989, Stern et al., 1984; Ternstrom and Molin, 1987
	Beef carcasses	50	Garcia et al., 1985
	Beef	0–5	Gill and Harris, 1984, Stern et al., 1984, Ternstrom and Molin, 1987
	Lamb	1–20	Stern et al., 1984
	Turkey	56–64	Rayes et al., 1983
	Chicken	8–89	Christopher et al., 1982b, Kinde et al., 1983, Norberg, 1981, Shanker et al., 1982, Stern et al., 1984, Ternstrom and Molin, 1987
	Raw milk	0.4–1.2	Davidson et al., 1989, Doyle and Roman, 1982, McManus and Lanier, 1987
	Fresh mushrooms	2	Doyle and Schoeni, 1986
Clostridium botulinum	Bacon	0.1	Hauschild and Hilsheimer, 1980
	Liver sausage	2	Hauschild and Hilsheimer, 1983
	Infant foods	0	Kautter et al., 1982
	Corn syrup	20	Kautter et al., 1982
	Honey	2	Kautter et al., 1982
Clostridium perfringens	Pork	0–39	Bauer et al., 1981; Ternstrom and Molin, 1987
	Cooked pork	45	Kokubo et al., 1986
	Beef	22	Ternstrom and Molin, 1987
	Chicken	0–54	Lillard et al., 1984, Ternstrom and Molin, 1987
	Seafoods	2.4	Abeyta, 1983
Enterovirus	Shellfish	0–47.8	Ellender et al., 1980, Gerba and Goyal, 1978, Goyal et al., 1979, Khalifa et al., 1986, Vaughn et al., 1980, Wait et al., 1983
Escherichia coli (enterotoxigenic)	Cheese	0	Glatz and Brudvig, 1980
	Raw milk	0	Glatz and Brudvig, 1980

Table 1. (continued)

Organism	Food	Percent positive	Reference
Escherichia coli O157 H7	Beef	3 7	Doyle and Schoeni, 1987
	Pork	1 5	Doyle and Schoeni, 1987
	Poultry	1 5	Doyle and Schoeni, 1987
	Lamb	2	Doyle and Schoeni, 1987
Listeria monocytogenes	Raw red meats	0–43	Buchanan et al., 1989, Ternstrom and Molin, 1987
	Ground beef	77	Farber et al., 1988
	Ground pork	95	Farber et al., 1988
	Ground veal	100	Farber et al., 1988
	Chicken	13–56	Bailey et al., 1989, Farber et al., 1988, Genigeorgis et al., 1989
	Turkey	12–18	Genigeorgis et al., 1990
	Cured meats and fermented sausages	0–20	Buchanan et al., 1989; Farber et al., 1989, Trussel, 1989
	Seafood	11–26	Buchanan et al., 1989, Weagant et al., 1988
	Raw milk	1 6–4 2	Davidson et al., 1989, Llewen and Plautz, 1988, Lovett et al., 1987
	Pasteurized milk	0	Farber et al., 1988
	Ice cream	0 25	Farber et al., 1988
	Raw whole egg	5	Leasor and Foegeding, 1989
	Produce and vegetables	0	Farber et al., 1989
Salmonella species	Beef	0–2 6	Lammerding et al., 1988, Ternstrom and Molin, 1987
	Veal carcasses	4 1	Lammerding et al., 1988
	Pork	0–18	Genigeorgis et al., 1989; Lammerding et al., 1988, Madden et al.,1986, Ternstrom and Molin, 1987
	Pork products	3–20	Duitschaever and Buteau, 1979; Farber et al., 1988
	Turkey carcasses	69	Lammerding et al., 1988
	Turkey sausage	100	Duitschaever and Buteau, 1979
	Chicken	0–100	Duitschaever and Buteau, 1979; Izat et al., 1989; Lammerding et al., 1988, Lillard et al., 1984; Norberg, 1981, Ternstrom and Molin, 1987
	Shellfish	3 7–33	Colburn et al., 1989, Fraiser and Koburger, 1984
	Fish	0	Fraiser and Koburger, 1984
	Raw milk	0 5–4 7	McManus and Lanier, 1987, McEwen et al., 1988
Staphylococcus aureus	Raw beef	16	Ternstrom and Molin, 1987
	Raw pork	13	Ternstrom and Molin, 1987
	Pork sausage	33	Farber et al., 1988
	Raw chicken	41–73	Lillard et al., 1984, Ternstrom and Molin, 1987
	Seafood	38	Abeyta, 1983
	Bakery items[b]	9 8	Sumner et al., 1993
Vibrio cholerae	Shellfish	7 4–33	Colburn et al., 1989; Tepedino, 1982
Vibrio parahaemolyticus	Seafood	2 8–46	Abeyta, 1983, Hackney et al., 1980
Yersinia enterocolitica[c]	Beef	2	Ternstrom and Molin, 1987
	Pork	2 5–49	Genigeorgis et al., 1989; Schiemann, 1980, Ternstrom and Molin, 1987
	Processed pork products	7–37	Delmas and Vidon, 1985, Schiemann, 1980
	Chicken	11–25	Norberg, 1981, Ternstrom and Molin, 1987
	Raw milk	2 7–48	Davidson et al., 1989, McManus and Lanier, 1987, Moustafa et al., 1983
	Pasteurized milk	1	Moustafa et al., 1983
	Ice cream	22	Delmas and Vidon, 1985
	Raw vegetables	46	Delmas and Vidon, 1985

[a]It was not shown that the *Aeromonas* isolates were pathogenic for humans
[b]Oatmeal raisin cookies, apple muffins, cream puffs, long johns
[c]Many strains of *Y. enterocolitica* isolated from foods are avirulent

Table 2. Selected current and new opportunities for improving food safety

Type of effort	Effort or opportunity	Impact on exposure	Location of impact	Currently proposed or recently initiated	Future Option
Educational	Safe food handling label for meat and poultry.	reduction	end-user: consumer, food service worker	X	
Educational	Package inserts which detail risk-benefit information targeted at high risk consumers.	avoidance by high-risk individuals	end-user: consumer, food service worker		X
Educational	Information dissemination (proper food handling, individuals at increased risk) into homes or grocery stores, for example through telecommunications and computer linkages.	reduction, avoidance by high-risk individuals	end-user: consumer, food service worker; grocer, distributor	X	X
Regulatory	Use HACCP systems to improve food safety.	prevention, reduction, and/or destruction	all levels except home, including producer, processor, distributor, grocer, and food service	X	

Type of effort	Effort or opportunity	Impact on exposure	Location of impact	Currently proposed or recently initiated	Future Option
Regulatory or market driven	Economic incentives for improved food safety.	prevention, reduction, destruction	all levels	X	X
Regulatory	Use of Good Manufacturing Practices	prevention, reduction, destruction	processor	X	
Production, processing or preservation methods	Use of new or updated processing and preservation approaches. Examples: organic acid carcass washes, irradiation, natural antimicrobials, high pressure processing, ohmic heating, aseptic packaging, competitive exclusion (to prevent animals from harboring pathogens in their intestines).	prevention, reduction, destruction	all levels	X	X
Production, processing or preservation methods	Use of newly developed rapid methods to detect pathogens and/or their toxins and continued development of methods which could be applied on-line during food processing.	prevention, reduction, destruction	all levels except home or end-user	X	X

Type of effort	Effort or opportunity	Impact on exposure	Location of impact	Currently proposed or recently initiated	Future Option
Educational/ information generation and dissemination	Development of quantitative risk assessment for acute and chronic diseases associated with foodborne pathogens.	prevention, reduction, destruction	all levels	X	X
Research, education and implementation	Development and use of animal identification and tracking systems to track pathogens through the food chain to their source.	prevention	all levels except home or end-user		X
Research, education and implementation	Development of new knowledge about the environmental niches and ecology of foodborne pathogens, their growth and survival capabilities, and their sensitivities to control procedures (heat, fermentation, or other).	prevention, reduction, destruction	all levels	X	X
Educational/ information generation and dissemination	Development of integrated databases (linking doctors offices, clinics and others both locally and nationally) to facilitate consensus regarding the magnitude of an outbreak and to more rapidly identify an outbreak which is in progress.	prevention, reduction, destruction	all levels	(proposed in the Centers for Disease Control and Prevention strategy for prevention of infectious disease)	X

Mr. TOWNS. Dr. Guzewich.

STATEMENT OF JOHN J. GUZEWICH, M.P.H., CHIEF, FOOD PROTECTION SECTION, NEW YORK STATE DEPARTMENT OF HEALTH

Dr. GUZEWICH. Thank you, Mr. Chairman and members of the subcommittee. Good morning. I am John J. Guzewich, chief of the food protection section of the New York State Department of Health. I would like to thank you for the opportunity to testify on the need to revamp the Federal food safety system.

My reasons for being here are to provide insight into current foodborne disease threats and how data from a well functioning foodborne disease surveillance network can provide a useful tool in determining food safety priorities.

In the interest of time, I will be skipping over some portions of my written statement. Analysis of the findings of our foodborne disease surveillance network has provided information to assist in setting program priorities since 1980. Our analysis convinced us that our traditional sanitation inspection approach emphasized the wrong factors. Therefore, we revised our inspection protocol, to emphasize a system based on analyzing hazards and establishing control points known as HACCP.

During the period 1980 to 1991, our foodborne disease surveillance system reported 1,528 outbreaks involving 31,675 cases of illness. An agent was identified in 1,036, or 68 percent, of these outbreaks. Viral agents accounted for 38 percent of the outbreaks and 45 percent of the cases of illness. Bacterial agents were reported in 47 percent of the outbreaks involving 53 percent of the cases, salmonellosis accounted for 23 percent of the outbreaks and 26 percent of the cases.

Contributing factors were identified in 675, or 44 percent, of the outbreaks; inadequate refrigeration is No. 1, reported in 24 percent of the outbreaks where factors were reported. Second in frequency was contaminated ingredients, meaning shellfish or eggs, being reported in 22 percent of the outbreaks. An infected worker was the fifth most commonly reported contributing factor at 18 percent. The finding that infected food workers contributed to so many foodborne disease outbreaks, supported legislation in 1991 that made New York State the first State to prohibit food worker bare-hand contact with ready-to-eat foods in restaurants.

The place where the implicated vehicle was contaminated or was misprepared was identified in 896, or 59 percent, of our outbreaks. Food service establishments and retail food stores were reported as the place of contamination in 63 percent of the outbreaks. Private homes were reported in 7 percent. Source water, which relates to shellfish and the like, was reported in 20 percent; food processing facility in 5 percent, and farms in 2 percent.

I believe that the biggest food safety issue the Federal Government faces today is the lack of an effective national system that can identify food safety issues and problems and uniformly coordinate a system that prevents foodborne illness.

Federal agencies are more likely to learn of dramatic regional or national foodborne disease crises. They don't have baseline infor-

mation to put the crises in perspective and to identify less dramatic but possibly more significant problems.

The first action needed is support for a coordinated national surveillance system for foodborne disease, one which earns everyone's confidence. The system needs to provide information Congress and the agencies can use as the basis for determining short and long-term priorities, and evaluating current protection programs. For this system to be successful, the Federal Government will need to have a single focal point at the national level.

The second action involves the Federal Government providing support to State and local surveillance and protection programs in the form of program funding including staff training, laboratory support, resources for community outreach. Until the Nation has a coordinated functioning system, it will not be prepared to detect emerging problems or anticipate and prevent problems before they get started.

Our experience teaches that microbial contamination of food is a much larger threat to public health than is chemical contamination. Food prepared in food service establishments is causing far more documented morbidity than is food prepared in federally regulated settings.

Salmonella is still the most significant foodborne disease pathogen due to the number of cases of illness and severity of illness it causes. Newly emerging pathogens, such as Escherichia coli 0157:H7 are certainly significant for the severity of illness if not for the number of cases reported.

The current system for food safety in this country is among the best in the world, but it could be improved by focusing on its primary mission, public health protection. There needs to be one consistent approach at the Federal level which creates and maintains an effective outreach with State and local agencies.

The program needs a national foodborne disease surveillance network that receives information from all surveillance sources and produces timely data that can be used as the basis for setting priorities. An effective regulatory program needs to be based on the HACCP approach. For the system to work, the Federal Government must incorporate its State and local counterparts as equal partners on the team, and they must provide monetary support for State and local foodborne disease surveillance and food safety regulatory programs.

Once again, thank you for this opportunity to testify. I would be happy to answer any questions that you have.

Mr. TOWNS. Thank you very much.

[The prepared statement of Dr. Guzewich follows:]

Testimony Before the Subcommittee on
Human Resources and Intergovernmental Relations
of the Committee on Government Relations
US House of Representatives
May 25, 1994

Statement of John J. Guzewich, R.S., M.P.H. Chief
Food Protection Section
Bureau of Community Sanitation and Food Protection
Center for Environmental Health
New York State Department of Health

Good morning, I am John J. Guzewich, Chief of the Food Protection Section of the New York State Department of Health. I would like to thank you for the opportunity to testify on the need to revamp the Federal food safety system. My reasons for being here are to provide insight into current foodborne disease threats and how data from a well-functioning foodborne disease surveillance network can provide a useful tool in determining food safety priorities.

Background

Systematic foodborne disease surveillance in New York State began in 1980 and is coordinated by the Department of Health's Bureau of Community Sanitation and Food Protection. It would be a mistake, however, to think of that Bureau as running the system, for the system actually consists of a network of state and local professionals, all focused on protecting the public's food supply. Depending on the type and location of an outbreak, teams from any of the 37 county and city health departments, nine state district health offices and three state regional health offices may be involved. Investigative teams may include surveillance officers, public health physicians, nurses, sanitarians, and epidemiologists.

Other governmental agencies also are part of our surveillance network. The NYS Department of Agriculture and Markets (NYSDA&M) provides assistance in reporting, outbreak investigation and laboratory testing. The NYS Department of Environmental Conservation tracks sources of shellfish involved in outbreaks. New York State, in turn, is part of a larger national system, working with agencies in other states and reporting outbreaks to the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Centers for Disease Control and Prevention (CDC). The state surveillance system also draws on investigation expertise and assistance for laboratory testing from these agencies.

Once an investigation has commenced, the Bureau coordinates information on a regular basis with the Department's Wadsworth Center for Laboratories and Research (Wadsworth), the Bureau of Communicable Disease Control, local surveillance program units, FDA, USDA, NYSDA&M, CDC, etc. Laboratory support is provided by Wadsworth for the majority of etiologic confirmation. In addition, many hospitals, local health department, county, and private labs contribute to the information gathered in an

investigation. Procedures for investigation of foodborne disease outbreaks in New York State follow the guidelines set up by the International Association of Milk, Food and Environmental Sanitarians, Inc.: "Procedures to Investigate Foodborne Illness," fourth edition (1987) and the Department's "Environmental Health Manual." Staff submit a final report to the Bureau for each investigation that identifies an association between consuming food and becoming ill. The Bureau reviews all reports for accuracy, validity of conclusions and completeness of information with follow-up back to the investigators as necessary. Data are reported to CDC and entered into the program's database after completing this review.

Analysis of the findings from our foodborne disease surveillance network has provided information to assist in setting program priorities since 1980. Our analysis convinced us that our traditional sanitation inspection approach emphasized the wrong factors; therefore, we revised our inspection protocol to emphasis a system based on analyzing hazards and establishing control points known as Hazard Analysis Critical Control Point (HACCP). Hazard Analysis Critical Control Point (HACCP) is a scientific and rational approach to assist food service operators to analyze potential hazards, determine the critical control points in a food process and develop monitoring procedures to determine if the hazards identified are being effectively controlled. HACCP represents an important food protection tool for regulatory agencies and industry. The recent completion of our compilation of 12 years of data will enable operators to prepare HACCP plans to address factors, including methods of preparation, significant ingredients and critical control points, identified as causing foodborne illness in New York State.

New York State Foodborne Disease Data 1980-1991

During the period 1980 through 1991, our foodborne disease surveillance system reported 1,528 outbreaks involving 31,675 cases of illness. An agent was identified in 1,036 or 68% of these outbreaks. Viral etiologies accounted for 38% of the outbreaks and 45% of the cases of illness. Our data are influenced by 215 molluscan shellfish outbreaks most of which occurred in the period 1982-1984 with suspect enteric viruses as the etiology in most instances. Bacterial etiologies were reported in 47% of the outbreaks involving 53% of the cases. Salmonellosis accounted for 23% of the outbreaks and 26% of the cases.

Contributing factors were identified in 675 or 44% of the outbreaks. Food temperature problems (e.g., inadequate refrigeration, inadequate cooking, inadequate hot-holding and improper cooling) are among the top ten most frequently reported contributing factors. Inadequate refrigeration is number one, reported in 24% of the outbreaks where factors were reported. Second in frequency was contaminated ingredients (e.g., shellfish or eggs) being reported in 22% of the outbreaks. We traced contaminated shellfish and eggs back to their respective source and then pressed the appropriate regulatory agencies and industries to resolve the problem. We also alerted consumers to the risks associated with eating raw or lightly cooked shellfish or eggs. An infected worker was the fifth most commonly reported contributing factor at 18%. The finding that infected food workers contributed to so many foodborne disease outbreaks, supported legislation in 1991 that

made New York State the first state to prohibit food worker barehand contact with ready-to-eat foods in restaurants.

Since Congress is interested in the relative public health importance of different points in the food distribution system, our data on the place where the implicated food vehicle was contaminated/or misprepared should be of interest. These locations were identified in 897 or 59% of our outbreaks. Food service establishments and retail food stores were reported as the place of contamination in 63% of the outbreaks, private homes were reported in 7%, source water (which relates to shellfish) was reported in 20%, food processing facility in 5% and farms in 2%.

Regulatory responsibility for shellfish harvesting is shared between the states and FDA. The states, FDA and USDA share the food processing facility component and the states and USDA share the farm responsibility. Regulatory responsibility for food service and retail food stores is a state and local role with the FDA providing technical advice. When Congress considers directing federal dollars to where the biggest need exists, state and local food service and retail food store programs deserve priority attention.

Although food service establishments are involved in most documented outbreaks, this may be due in part to the nature of the surveillance system. These places concentrate the exposure that creates an outbreak, though the origin is often facilities back down the food chain, out of sight. Many restaurant outbreaks involve food of animal origin and agents that are associated with those animal foods. If the level of pathogen contamination on raw animal foods could be lowered, we would have fewer restaurant outbreaks.

The National Food Safety Problem

I believe that the biggest food safety issue the federal government faces today is the lack of an effective national system that can identify food safety issues and problems and uniformly coordinate a system that prevents foodborne illness. The Centers for Disease Control recently released a report on the weak condition of infectious disease surveillance in the country. CDC's foodborne disease surveillance program is a piece of that problem. CDC has so little confidence in the foodborne disease data that is submitted to them from the states that it is not frequently published and is rarely analyzed. Adding to the problem is the fact that the FDA and USDA have their own surveillance programs for the products they regulate. The FDA and USDA conduct investigations and rarely tell the state or local health authorities of their activities. Many state and local agencies have poor foodborne disease surveillance programs or none at all. The result is a system in chaos. The situation is analogous to two blind men each holding a different end of an elephant and each one trying to describe what they are holding onto. The federal food agencies know that Escherichia coli O157:H7 is a problem in hamburgers in the northwest and that Salmonella enteritidis is a problem in shell eggs in the northeast, but, they don't know what the foodborne disease problems are in the U.S.

The first action needed is support for a coordinated national surveillance system for foodborne disease, one which earns everyone's confidence. This

system needs to provide information Congress and the agencies can use as the basis for determining short and long term priorities and evaluating current protection regulatory programs. For this system to be successful, the federal government will first need to have a single focal point at the national level. The second action involves the federal government providing support to state and local surveillance and protection programs in the form of program funding including staff training, laboratory support and resources for community outreach. Until the nation has a coordinated, functioning system, it will not be prepared to detect emerging problems or anticipate and prevent problems before they get started.

Your letter of invitation requested my view of the current public health risks associated with food. Our experience teaches that micobiologial contamination of food is a much larger threat to public health than is chemical contamination. Food prepared in food service establishments is causing far more documented morbidity than is food prepared in federally regulated settings such as meat plants and food processing facilities, and yet little federal money is spent to support state and local regulatory programs that attempt to deal with this problem. Salmonella is still the most significant foodborne disease pathogen due to the number of cases of illness and severity of illness it causes. Viral foodborne disease agents cause a significant percentage of foodborne disease cases, although most are mild in nature. Newly emerging pathogens, such as Escherichia coli O157:H7 are certainly significant for the severity of the illness, if not for the number of cases reported. If we had a truly effective salmonella control program from farm to table, we wouldn't have much of a E. coli O157:H7 problem. That is because the same controls that work for salmonella would also coincidentally control E. coli O157 :H7. Processed food, which is more likely to be federally regulated, poses much less of a risk. When a problem does occur with processed foods, it can affect large numbers of people, however. Imported foods, particularly those from developing countries, do pose a potential threat; but, with the exception of mushrooms canned in The People's Republic of China, and a recent case of contaminated tea from Paraguay, we haven't documented a foodborne disease problem with these foods in New York.

The current attention on seafood safety is not well focused. Ingestion of raw or partly cooked shellfish poses the greatest opportunity for disease transmission. Control efforts must focus on the quality of harvest waters, preventing illegal harvesting and alerting consumers of the risks of eating raw or lightly cooked shellfish. Concerns over finfish involve scombroid fish poisoning associated with sports caught bluefish and tuna and ciguatera fish poisoning associated with tropical reeffish. Otherwise, finfish are not being documented as a foodborne disease problem.

The existing federal food safety regulatory system is divided along product or commodity lines and lacks a consistent focus on public health protection. Food safety should be achieved through a comprehensive coordinated approach that views food in a continuous system from farm or water to table, following the public health principles of multiple barriers embodied in the HACCP system. We can't afford to continue to struggle with multiple agencies, each with different and sometimes conflicting agendas and approaches. We need a system where federal, state and local food safety agencies have close and well established working relationships so that

programs are well integrated and not du[illegible]ting in some areas while leaving gaps in others.

Conclusion

The current system for food safety in this country is among the best in the world, but, it could be improved by focusing on its primary mission-public-health protection. There needs to be one consistent approach at the federal level which creates and maintains an effective outreach with state and local agencies. The program needs a national foodborne disease surveillance network that receives information from all surveillance sources and produces timely data that can be used as the basis for setting short and long term regulatory priorities. An effective regulatory program needs to be based on the HACCP approach. The new FDA Model Food Code embraces this approach. Its adoption and implementation by the states, however, require additional resources and national assistance. For the system to work, the federal government must incorporate its state and local counterparts as equal partners on the team and they must provide monetary support for state and local foodborne disease surveillance and food safety regulatory programs.

Once again, thank you for this opportunity to testify and I would be happy to answer any questions you have.

Acknowledgements

I would like to acknowledge the contribution of John Fudala, a Principal Sanitarian on my staff, who coordinates our foodborne disease surveillance network; the staff in our local health departments and the state, and the Department of Agriculture and Markets. We often rely on information from the departments of health and agriculture in other states; experts at several universities; the Centers for Disease Control; the Food and Drug Administration and U.S. Department of Agriculture. Coordinated teamwork is essential to resolve food safety issues.

I would also like to recognize the work done by Steven Weingold, a graduate student in the School of Public Health at the State University of New York at Albany, who compiled the information on our foodborne outbreaks between 1980 and 1991 that I will be reporting on today. Mr. Weingold's project was paid for by the Division of Federal/State Relations in the U.S. Food and Drug Administration.

94132PRO0647

STATEMENT OF GARY HLADY, M.D., DIRECTOR, COMMUNICABLE DISEASE EPIDEMIOLOGY, STATE OF FLORIDA

Dr. HLADY. I am Gary Hlady, I am the director of communicable disease epidemiology for the State of Florida.

I have brought some visuals here. I would like to have the first slide please.

I would like to emphasize these four points today about vibrio vulnificus. First, vibrio vulnificus is a natural contaminant of raw oysters and a leading cause of death from foodborne illness.

Second, there is no method to assure that raw oysters harvested during warm weather months do not contain vibrio vulnificus.

Third, there is nothing in the FDA proposed HACCP system that will prevent food poisoning by vibrio vulnificus.

Finally, Federal Government action is needed to assure that all oysters reaching the marketplace are safe.

Next slide please. Vibrio vulnificus is not a result of pollution or any other human activity, and 100 percent of oysters harvested from the Gulf of Mexico during the summer months may contain vibrio vulnificus.

This graph shows that last year's oysters from Apalachicola Bay have levels of vibrio vulnificus as high as 240,000 organisms per gram. There is no safe level established, and death has resulted from consumption of oysters containing less than 1,000 organisms per gram and from eating as few as three contaminated raw oysters.

Next slide please. From 1981 through 1993, 76 persons in Florida were infected with vibrio vulnificus from raw oysters and 38 of them died. This makes vibrio vulnificus one of the most deadly infections known, and the single leading cause of reported deaths from foodborne illness in Florida.

Next slide please. At least 14 States have reported vibrio vulnificus infections from raw oysters since 1981 with an estimated 48 cases and 24 deaths in the United States each year.

Vibrio vulnificus is not an equal opportunity killer. People with liver disease are at greatest risk, but others with illness of the stomach or blood or immune disorders such as diabetes or AIDS are also susceptible. As many as 25 percent of the U.S. population may be at some increased risk of vibrio vulnificus infection for one reason or another.

Next slide please. Risk estimates using Florida data show that raw oyster eaters without liver disease are at only slightly increased risk of illness from vibrio vulnificus. That is the middle bar there on the graph. But the risk for raw oyster eaters with liver disease is 80 times greater.

Next slide please. The findings are even more striking with regard to the risk of death, where the risk for raw oyster eaters with liver disease is over 200 times the risk for raw oyster eaters without liver disease. Because vibrio vulnificus is not the result of pollution, current procedures to certify the safety of raw oysters are not sufficient to assure that contaminated oysters will not reach the marketplace, but the occurrence of vibrio vulnificus appears to be seasonal.

Next slide please. As we see here, the majority of illnesses occur from May through October. This suggests that effective preventive

measures may include limiting oyster harvest to the cold weather months or cooking all oysters harvested during warm weather months.

Next slide please. In the absence of such restrictions, the States of Florida, California, and Louisiana now require point of sale warnings such as this one to alert raw oyster consumers who may be at risk.

The HACCP system proposed by FDA is another attempt to improve seafood safety, but because it deals only with seafood processing, it will have no effect on the number of oysters which contain vibrio vulnificus at the time of harvest.

There is currently no available method to process raw oysters in a way which preserves the raw product but eliminates vibrio vulnificus.

Next slide please. Because raw oysters containing vibrio vulnificus are distributed and consumed throughout the United States, further action at the Federal level is needed to prevent additional illness and deaths.

There is an immediate need for an effective national policy to warn and educate consumers who may be at greatly increased risk from raw oyster consumption.

There is also a need for the Federal Government to establish tolerance or action levels for vibrio vulnificus in oysters, and to promote the development of practices and procedures that assure all oysters reaching the marketplace meet consumer expectations for food safety.

Thank you very much for your attention.

Mr. TOWNS. Let me thank you.

[The prepared statement of Dr. Hlady follows:]

Vibrio vulnificus from Raw Oysters: A Leading Cause of Reported Deaths from Foodborne Illness

by

W. Gary Hlady, MD, MS
Director of Communicable Disease Epidemiology
State Health Office
Department of Health and Rehabilitative Services
State of Florida

presented as testimony
to the
Human Resources and Intergovernmental Relations Subcommittee
of the
Committee on Government Operations
House of Representatives
Congress of the United States

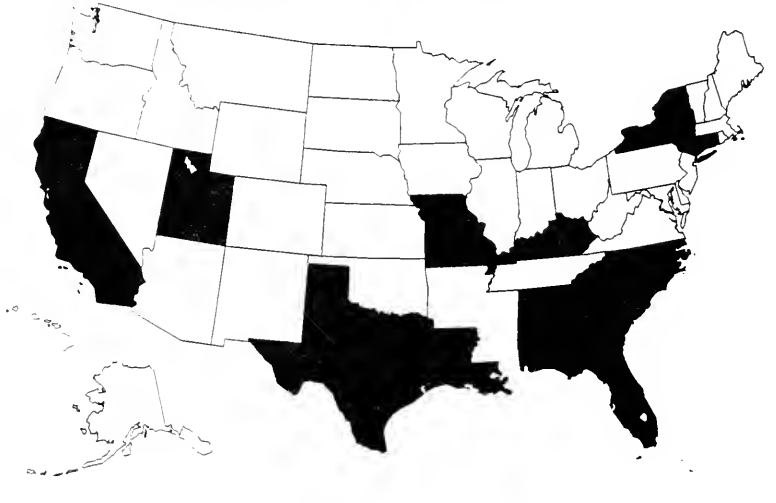
May 25, 1994

Nature, extent, and risks of *Vibrio vulnificus* infections

Vibrio vulnificus is a naturally occurring marine bacterium which is often found in oysters, especially those harvested from the Gulf of Mexico. It is not a result of pollution or any other human activity.

When raw oysters containing *Vibrio vulnificus* are consumed by susceptible individuals, severe illness may result. From 1981 through 1992, 72 persons in the State of Florida were infected with *Vibrio vulnificus* from raw oysters, 36 (50%) of them died, making *Vibrio vulnificus* one of the most deadly foodborne illnesses known and the single leading cause of reported deaths from foodborne illness in Florida. Nationwide, 14 states have reported infections with *Vibrio vulnificus* from raw oysters since 1981. The U.S. Food and Drug Administration (FDA) estimates there are an average of 48 cases of *Vibrio vulnificus* infection from raw oysters in the U.S. each year, with 24 deaths.

States Reporting *Vibrio vulnificus* Infections from Raw Oysters: 1981 - 1992

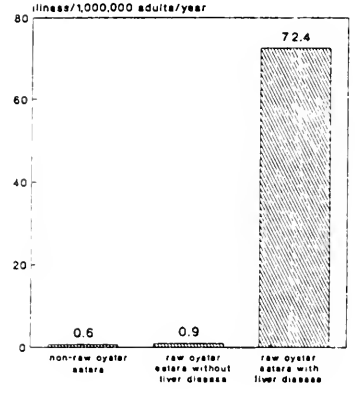


Source: US Food and Drug Administration

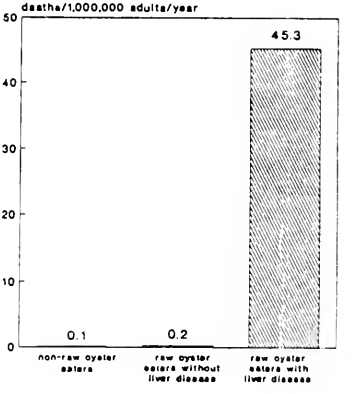
Certain individuals are at greatly increased risk of illness and death from eating raw oysters containing *Vibrio vulnificus*. These are predominantly people with liver disease, but also include people with illnesses of the stomach or blood, or immune disorders resulting from conditions such as diabetes or AIDS.

Risks of illness and death from *Vibrio vulnificus* infections from raw oysters in Florida were calculated using reported cases from 1981-1992 along with census data and information from the 1988 Behavioral Risk Factor Survey. Results showed that raw oyster eaters without liver disease were at only slightly increased risk of illness from *Vibrio vulnificus*, but that raw oyster eaters with liver disease were at 80 times greater risk of illness and over 200 times greater risk of death from *Vibrio vulnificus* infection. [For comparison, smokers suffer only a 20 to 30 times greater risk of death from lung cancer.] In Florida, approximately 71,000 people who are aware they have liver disease also eat raw oysters. Many others, especially heavy drinkers, may have liver disease without their knowledge. The proportion of people nationwide who may be at some increased risk of *Vibrio vulnificus* infection from raw oyster consumption has been estimated as high as 25%.

Estimated annual risk of illness due to *V. vulnificus*



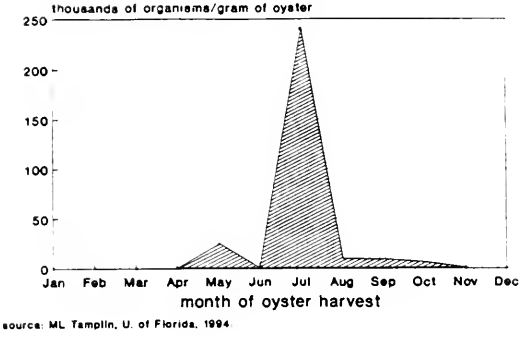
Estimated annual risk of death from *V. vulnificus* infection



Ways to prevent *Vibrio vulnificus* infections

Because *Vibrio vulnificus* is not a result of pollution or fecal contamination, current procedures to certify the safety of raw oysters are not sufficient to assure that oysters containing *Vibrio vulnificus* will not reach the marketplace. In fact, recent evidence indicates that 100% of oysters harvested from the Gulf of Mexico during the summer months may contain *Vibrio vulnificus*. During 1993, oysters harvested from the largest production area in Florida showed levels of *Vibrio vulnificus* as high as 240,000 organisms per gram. There is no safe level of *Vibrio vulnificus* established and the most recent death due to *Vibrio vulnificus* in Florida resulted from consumption by a high-risk individual of oysters from a lot containing only 930 organisms per gram. Death has resulted from eating as few as 3 contaminated raw oysters.

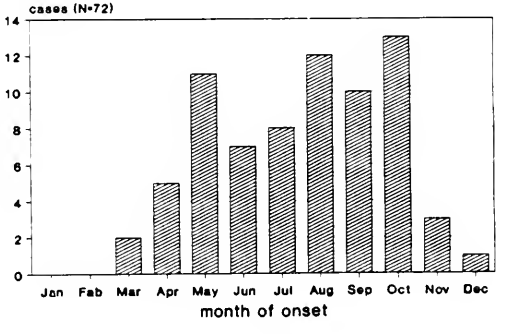
V. vulnificus in Apalachicola, Florida oysters, 1993



source: ML Tamplin, U. of Florida, 1994

The occurrence of *Vibrio vulnificus* appears to be related to water temperature, with levels dipping below the detectable range during the winter months. The majority of illnesses due to *Vibrio vulnificus* in Florida have occurred from May through October. This suggests that limiting harvest of oysters to the cold weather months or assuring that all oysters harvested during warm weather months are cooked may be effective preventive measures. Thoroughly cooked oysters are safe for everyone. In the absence of such restrictions, the State of Florida, along with the states of California and Louisiana, now require point-of-sale warnings to raw oyster consumers who may be at risk for *Vibrio vulnificus* infection.

V. vulnificus infection from raw oysters Florida, 1981-1992

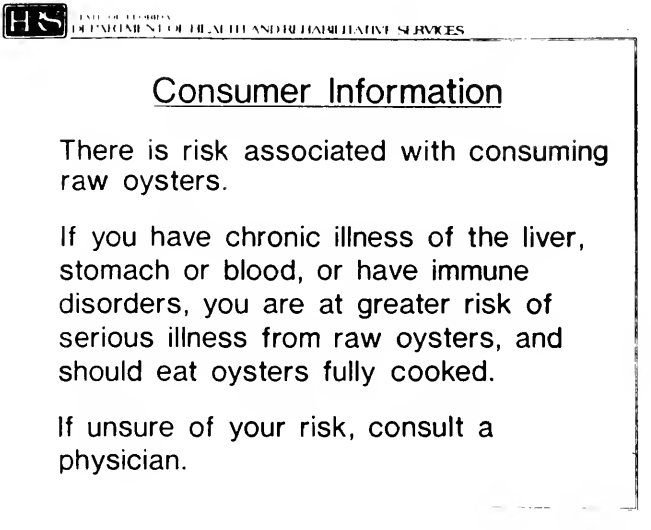


The impact of HACCP

Because the Hazard Analysis Critical Control Point (HACCP) system proposed by the FDA for seafood deals only with seafood processing, it will have no effect on limiting the number of raw oysters which contain *Vibrio vulnificus* at the time of harvest. There is no currently available method to process raw oysters in a way which preserves the raw product but eliminates *Vibrio vulnificus*.

The need for further Federal government action

Raw oysters containing *Vibrio vulnificus* are distributed and consumed throughout the United States. There is, therefore, an immediate need for an effective national policy to warn and educate consumers who may be at greatly increased risk of serious illness and death. Further, there is a need for the Federal government to establish tolerance/action levels for *Vibrio vulnificus* in oysters and to promote development of practices and procedures to assure that all oysters reaching the marketplace meet consumer expectations for food safety.



Mr. TOWNS. Let me thank all of you for your testimony. I have a few questions that probably could be answered with just a yes or no.

Would all of you agree that microbial contamination is the primary food safety concern in the United States today?

Dr. FOLGEDING. Yes.

Dr. HLADY. Yes.

Dr. GUZEWICH. Yes.

Mr. TOWNS. Would you all agree that the problem of microbial contamination is getting worse?

Dr. FOEGEDING. I would not necessarily agree with that.

Mr. TOWNS. A little yes and a little no?

Dr. FOEGEDING. I don't think we have the data to know that.

Dr. GUZEWICH. I agree. We don't have enough information, Mr. Chairman, to know. That is the point of my testimony.

Mr. TOWNS. Would you all agree that microbial contamination is a growing problem on nontraditional sources such as fresh fruits and vegetables?

Dr. GUZEWICH. I think we are becoming more aware of the problem.

Dr. FOEGEDING. I agree with that, but we do not know if it is growing.

Mr. TOWNS. Do you think Federal food safety efforts should be consolidated into a single agency?

Dr. FOEGEDING. That is my personal opinion. I believe that the number of agencies involved cause confusion because they don't speak with a uniform voice that is understood by the industry and the public.

Dr. GUZEWICH. That is my personal opinion also, Mr. Chairman. I think that agency has to be a public health agency.

Dr. HLADY. I would agree.

Mr. TOWNS. Should shellfish be labeled to warn high-risk consumers about the hazards of consuming it raw?

Dr. HLADY. We have already taken that step in Florida, along with the States of Louisiana and California.

Mr. TOWNS. So yes?

Dr. HLADY. Yes.

Dr. GUZEWICH. Yes, sir.

Dr. FOEGEDING. I believe they should be. I might add that, if I could, I think an analogy could be made to consumption of raw milk. Most States don't allow consumption of raw milk. It has been well recognized that raw animal foods in particular are often associated with hazardous organisms or hazardous organisms are associated with the foods.

Mr. TOWNS. Is the Federal Government targeting its resources to the greatest foodborne risk to public health?

Dr. FOEGEDING. I am not sure that I have the information to answer that. I am not well aware of how resources are distributed.

Dr. GUZEWICH. I know they can't get the job done. I am not sure how much a function that is of targeting resources, sir, but I know the job isn't being done.

Dr. HLADY. I also don't have enough information to really comment on that.

Mr. TOWNS. OK. Let me just move to you, Dr. Hlady. According to your statement, the estimated annual risk of vibrio vulnificus infection from raw oysters consumption is much higher than FDA's estimate which you also cite. Can you explain the difference?

Dr. HLADY. I am sorry, I don't know which figures you are referring to.

Mr. TOWNS. In your written statement you indicated, and I want to know could you explain the difference, it was in your written statement.

Dr. HLADY. The estimates of risk in my statement were based on Florida data, and the FDA estimates may be based on national data.

Mr. TOWNS. OK, right. Thank you. That explains it.

Would FDA's proposed HACCP regulations solve the problem?

Dr. HLADY. No, I certainly do not.

Mr. TOWNS. OK, let me thank you all. Well, maybe let me ask you another question. Why not?

Dr. HLADY. Because the problem is that vibrio vulnificus is in the oysters at the time they are hauled up on the boat, and the HACCP system addresses only what happens to the oysters after they are harvested. It does not address their condition at the time of harvest.

Mr. TOWNS. Right. OK, thank you very much.

At this time I yield to my colleague, Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

Mr. Chairman, just one thing I would like to ask about because I think the testimony of the witnesses has been very comprehensive, especially along with your questions, but the discussion here has centered around raw shellfish, particularly oysters. There is a burgeoning around the United States of sushi, which as you know is usually—I think there are some exceptions, but it is usually served raw. Are there any reports that you know of of any experienced difficulty in any quantifiable numbers, or to reverse that, obviously in Japan there is probably a great deal of consumption of raw fish there in that form. Is that the cause of a microbiology-caused infection?

Dr. FOEGEDING. In Japan, the No. 1 cause of reported foodborne illness is due to vibrio. It happens to be a different species than we have been discussing this morning, and that is vibrio parahemolyticus, but it is also an organism that is naturally occurring in ocean waters and it is a natural contaminant of the fish, so there is clear evidence that consumption of raw fish can lead to foodborne illness.

Mr. SCHIFF. In this country do you have any kind of mounting evidence of that particular food causing a problem?

Dr. FOEGEDING. Probably the data is available, but I am not sure I am aware of it.

Dr. HLADY. We haven't seen it as a significant problem in the State of Florida.

Dr. GUZEWICH. The nature of the diseases, Congressman, are parasitic mostly that are associated with the raw fish consumption, and the parasitic diseases are not reportable diseases in the public health system. Reportable diseases, meaning ones that are required

to be reported by physicians to the health department, and so we don't really have the information to answer your question.

This is an illustration of the problem, which was the subject of my testimony, we don't really have a system to collect that data so we can give you a good answer on that.

I would suspect that some people are made ill from the parasites that are found in fish. The Food and Drug Administration recently had an article published in a scientific journal by some of their scientists in the Seattle area documenting the relatively, surprising to me, high incidence of contamination of raw fish in sushi restaurants that had these parasites in them.

We have an issue in New York State where we prohibit barehand contact with ready-to-eat food. We have been enforcing that standard in sushi restaurants because workers can transmit a number of infections through their hands when they touch the food. That has been an issue for us because the sushi restaurants are not in favor of that because they feel that culturally it detracts from the preparation of the food, but I believe there would probably be some transmission there as well. But given the nature of our surveillance system, we don't really have information that we can give you meaningful data on.

Dr. FOEGEDING. If I may, I concur with that, and it is just not that the parasites are not reportable, but most of the viral and bacterial microbial problems are not reportable, either, so the data base is lacking.

Mr. SCHIFF. I want to thank the witnesses. I yield back, Mr Chairman.

Mr. TOWNS. Thank you very much.

Let me just say that I would like to thank the witnesses for their testimony. You have been very, very helpful in so many ways, and you also pointed out that we have some very serious problems that need to be corrected as well. So let me thank you for the information that you shared with us. Thank you.

I would like to call our third panel to the table, Dr. Fred Shank Director of the Center for Food Safety and Applied Nutrition, Food and Drug Administration.

Dr. Shank, will you identify the members that accompany you and will be testifying.

Mr. SHANK. Yes, I intend to during my opening statement, sir.

Mr. TOWNS. OK. All of them that will be participating, let me swear you in. Will you raise your right hands.

[Witnesses sworn.]

Mr. TOWNS. Please take your seat. Let the record reflect that the witnesses answered in the affirmative.

Let me thank you very much for being with us today and let me say, Dr. Shank, that we will give you 10 minutes to summarize your statement and then we will move to questions.

STATEMENT OF FRED R. SHANK, Ph.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY TOM BILLY, DIRECTOR, OFFICE OF SEAFOOD; PHILIP DERFLER, ASSOCIATE CHIEF COUNSEL FOR FOODS, DEPARTMENT OF HEALTH AND HUMAN SERVICES; PAUL BLAKE, CHIEF, ENTERIC DISEASES BRANCH, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. SHANK. Thank you, Mr. Chairman, and good morning, members of the subcommittee. I am Fred Shank, Director of the Food and Drug Administration——

Mr. SCHIFF. Mr. Chairman, I apologize for interrupting Dr. Shank, but if the people with you have been introduced I think I——

Dr. SHANK. That is the next thing.

Mr. SCHIFF. I apologize, excuse me.

Dr. SHANK. I am Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition. With me today is Mr. Tom Billy to my left, who is Director of the Office of Seafood within our center. We also have Mr. Philip Derfler, who is Associate Chief Counsel for Foods with the Department of Health and Human Services. He is on my far right. And Dr. Paul Blake, Chief of the Enteric Diseases Branch of the Centers for Disease Control and Prevention is to my immediate right.

We appreciate the opportunity to discuss the role of the Department of Health and Human Services and in particular the Centers for Disease Control and Prevention and FDA in the Federal food safety programs.

Your letter of invitation asked a number of questions about foodborne illness and the safety of the Nation's food supply. Let me assure you that the Nation's food supply is safe, wholesome, and abundant.

Some would like to take the stance that safe means no occurrence of foodborne illness. While that is our goal, its achievement is currently not realistic. Foodborne illnesses originate from a variety of sources, pathogenic microorganisms represent the most widely recognized source, but there are others. Some are naturally occurring toxicants, others are chemical contaminants, and in addition food production practices, processing, storage, distribution, handling, and home preparation techniques either individually or in combination have the potential to serve as a source of illness.

In the area of food safety, the mission of CDC is to determine foodborne microorganisms that cause pathogenesis, characterize the epidemiological and clinical nature of the illnesses, and, third, to identify risk factors for infection.

FDA's mission is to ensure that foods are safe, wholesome and sanitary, that foods are honestly, accurately and informatively represented, that noncompliance is identified and corrected, and that any unsafe products are removed from the market. It is with these goals in mind that CDC's and FDA's food safety programs—regulatory, surveillance, Federal-State cooperative efforts, research and educational—it is with this in mind that our programs are developed and carried out.

Our colleagues at the U.S. Department of Agriculture, responsible for ensuring the safety of meat poultry and eggs, are working cooperatively with CDC and FDA on such efforts as surveillance, consumer education, the food code, and safe handling instructions on labels. FDA works with other organizations such as the Environmental Protection Agency in carrying out those responsibilities.

State and local food regulators provide regulatory oversight in the vast retail segment of the food industry—the million plus restaurants, grocery and convenience stores, vending operations and institutional food suppliers. These States and local agencies are an integral part of the overall food safety umbrella.

I would like to present very briefly some background information on foodborne illness.

Foodborne illness is not a new form of disease, nor is it one dimensional.

FDA estimates that 24 to 81 million people become ill from microorganisms in foods, resulting in 9,000 unfortunate deaths. This is an annual cost to our society in the area of $23 billion.

The susceptibility to the severity of, foodborne illness is a very complicated interaction between what is eaten, the contaminant, the physical condition of the consumer, and even his or her genetic makeup. For many victims, foodborne illnesses cause only discomfort. However, in some, especially preschool aged children, the elderly in health care facilities and those with impaired immune systems, foodborne illness is more serious and may be life threatening, as we have heard this morning.

The science of epidemiology is providing the regulatory community with new information, often through the use of sophisticated genetic techniques, which help us identify weaknesses in our system and point where preventive intervention strategies may be applied.

CDC's surveillance program: Effective surveillance is the key to tracking our progress toward these goals. Such surveillance provides policymakers and health professionals with the basis for developing, implementing, and evaluating control policies, that will lead to a healthier United States in the new millennium.

CDC, in partnership with representatives from health departments, other Federal agencies, medical and public health professional associations, and international organizations have developed a strategic plan entitled "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States." The plan emphasizes surveillance, applied research, prevention and control, and public health infrastructure. I would like to submit a copy of the executive summary of this plan for the record.

Mr. TOWNS. Without objection.

[The information can be found in appendix 5.]

Dr. SHANK. Now I would like to turn to FDA's regulatory strategy which has over the years enhanced the safety of the food supply.

Although the current food supply, the current food safety assurance programs have functioned effectively, it is now facing new stresses and challenges, and here are just a few examples: New food processing and packaging technology, such as the use of modified atmosphere to prolong the shelf life and maintain the quality

of vegetables may enable anaerobic organisms to proliferate. The food supply has become more global. Now about 135 different countries supply seafood to the United States. We are faced with environmental pollution in some areas which we historically rely on to supply our food.

At the core of FDA's food safety program is its inspectional strategy. The current strategy, with its emphasis on periodic visual inspection of food facilities supplemented with end-product testing, was designed to control the problems that were known to exist when the Food, Drug, and Cosmetic Act was passed in 1938. This approach was effective for its time, but it is relatively resource intensive and has been criticized as being "inefficient" in today's world.

On January 28 of this year, FDA proposed new regulations to establish mandatory HACCP controls to ensure the safety of seafood products sold commercially in the United States. FDA proposed that domestic and foreign processors and importers adopt HACCP controls to prevent hazards that could affect the safety of these seafood products. The comment period on this proposal will close on May 31.

Because we believe that the future of food safety lies along the HACCP road, we also are exploring ways to extend HACCP beyond seafood. We have begun to try to build a consensus within other parts of the regulated food industry itself. After all, it is the industry's legal obligation to produce safe food. The government's regulatory role is one of providing oversight.

HACCP is a new way to carry out traditional agency duties. With implementation of the HACCP concept, FDA has stepped back and taken a broader view of food safety. Some people feel that the only thing that will improve upon the current system is more inspections and increased regulations. While I do not wish to downplay the importance of inspections and the enforcement of regulations, I think it is no longer practical to view food safety solely within this framework. In fact, I believe that stepping back and taking a careful look at the big picture is part of the message that comes through with the Vice President's report on reinventing government.

So FDA has begun to look into other areas where we might make better use of our resources by pooling resources where we can. The way we can work "smarter" is to take every advantage of existing expertise. FDA's new model food code embodies this new "better, smarter" philosophy. This document, published in January 1994, provides the most up-to-date advice to the States on assuring food safety in the retail setting. The food code also incorporates a framework for the application of HACCP at retail.

Another example is the way FDA and USDA approach consumer education. It is difficult for government to inform adequately all food service workers and the general American public about the best ways to prevent foodborne disease. For that reason, the agencies are increasing their efforts to work with other public and private sector organizations to ensure that information on proper food handling practices are widely communicated.

FDA and USDA, working closely with CDC, are increasing their dialog with thousands of State and local health and regulatory

agencies. For example, video teleconferences were conducted on September 2 of last year and May 19 of this year for State and local officials to interact directly with FDA and USDA experts.

In summary, the goal of a strong, effective food safety program is public health. While implementation of HACCP will help meet today's public health challenges, the combination of advancing technology, changing consumer demands, and the advent of a global marketplace continues to exert pressure for further changes.

Increasing resource demands define the need for increased cooperation among public health agencies and other groups to strengthen food safety programs and to direct them for the future.

This concludes my opening remarks. My colleagues and I would be happy to respond to your questions. Thank you.

Mr. TOWNS. Thank you very much, Dr. Shank.

[The prepared statement of Dr. Shank follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

FRED R. SHANK, Ph.D.

DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES
AND INTERGOVERNMENTAL RELATIONS

COMMITTEE ON GOVERNMENT OPERATIONS

U.S. HOUSE OF REPRESENTATIVES

MAY 25, 1994

TO BE RELEASED ONLY UPON DELIVERY

Mr. Chairman and members of the subcommittee:

Thank you for the opportunity to discuss the role of the Department of Health and Human Services (DHHS) and in particular the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in Federal food safety programs. Your letter of invitation asked a number of questions about foodborne illness and the safety of the Nation's food supply.

Let me assure you that the Nation's food supply is safe, wholesome and abundant. Some would like to take the stance that "safe" means no occurrences of foodborne illness. While that is our goal, its achievement is not realistic. The Public Health Service has a coordinated approach to assessing food safety, consisting of risk assessment and risk reduction. CDC performs risk assessment and FDA performs the risk reduction function.

In the area of food safety, the mission of CDC is to :

- determine foodborne microorganisms that cause pathogenesis,
- characterize the epidemiology and clinical nature of the illnesses, and
- identify risk factors for infection.

FDA's mission is to ensure that:

- foods are safe, wholesome, and sanitary;
- food products are honestly, accurately, and informatively represented;
- these products are in compliance with the law and FDA regulations;
- noncompliance is identified and corrected; and
- unsafe or unlawful products are removed from the market.

It is with these goals in mind that CDC's and FDA's food safety programs - regulatory programs, surveillance programs, federal/state cooperative programs, research programs, and educational programs - are developed and carried out.

Our colleagues at the United States Department of Agriculture (USDA) are working cooperatively with CDC and FDA on such efforts as surveillance, consumer education, the Food Code, and safe handling instructions on labels. FDA's work with the Environmental Protection Agency (EPA) and USDA has now resulted in an Administration proposal on better ways to regulate pesticides and their residues in food. These are illustrations of many other food safety initiatives with other departments and agencies across the federal government.

State and local food regulators provide regulatory oversight of the vast retail segment of the food industry -- the million

plus restaurants, grocery and convenience stores, vending operations and institutional food providers. These State and local agencies are an integral part of the overall food safety "umbrella."

In order to provide you with a better understanding of the character of foodborne illness, I would like to present some background information.

Background

Foodborne illness originates from a variety of sources. Pathogenic microorganisms represent probably the most widely recognized source. But there are others. Some are naturally occurring toxicants, e.g. ciguatoxin in certain species of finfish. Others are chemical contaminants introduced literally by the "hand" of man. In addition, food production practices, processing, storage, distribution, handling and home preparation techniques either individually or in combination have the potential to be a source of illness.

Foodborne illness is not a new form of disease, nor is it one-dimensional. Foodborne illness has been with us as long as man has walked the earth. In the United States, foodborne microbial illness is a major cause of personal distress, preventable death, and avoidable economic burden. FDA

estimates that 24 to 81 million people become ill from microorganisms in food, resulting in 9,000 deaths every year. The annual cost of foodborne illness is estimated by FDA to be between $7.7 and $23 billion.

The susceptibility to and severity of foodborne illnesses involve complicated interactions between what is eaten, the contaminant and the physical condition and genetic makeup of the consumer. For many victims, foodborne illness causes only discomfort or lost time from the job. However, for some, especially preschool age children, the elderly in health care facilities, and those with impaired immune systems, foodborne illness is more serious and may be life threatening. Developing fetuses, diabetics, and alcoholics are also at greater risk of severe illness or death.

Control of foodborne microbial pathogens is particularly elusive, despite the public health controls already in place, because microorganisms continue to adapt and evolve, often increasing their degree of virulence. Just a century ago, Louis Pasteur demonstrated that garlic inhibited growth of the strain of botulinal bacteria that existed in his time. Now, we have encountered a new strain that can live and grow in garlic. Numerous examples of microbial adaptability can be readily seen in the list of microorganisms which "emerged" as pathogens of major concern in the last few years - Listeria, Campylobacter

and E. coli O157:H7.

Epidemiology is providing the regulatory community with new information, often through the use of sophisticated genetic techniques, which help us identify weaknesses in our system and points where preventive intervention strategies may be applied. For example, CDC's matching of genetic information from Listeria isolated from patients with that of Listeria from foods in victims' refrigerators, was instrumental in making the linkage between human disease and foods from grocery store delicatessens. Only with such knowledge can industry develop and implement appropriate HACCP controls for those products, as well as consumer education strategies to further protect at risk consumers.

In general, when public health issues are being ranked by the experts, chemical issues generally fall below biological hazards. However each is a separate and important source of potential public health problems and within the context of a risk-based food safety program each must be considered and dealt with appropriately. At one end of the human health spectrum, biological hazards usually produce an immediate, acute effect, sometimes involving many people in a single episode, with reactions ranging from gastrointestinal upset to death. At the other end of the spectrum, chemical hazards - carcinogens, teratogens, mutagens - may take a lifetime to

manifest themselves as disease or may even show a delayed effect as genetic changes in the next generation.

In trying to control both biological and chemical hazards, we have learned that interrelationships exist that must be recognized when formulating strategy to deal with either hazard. For example, elimination of a potential chemical hazard may, inadvertently, increase the likelihood of a biological hazard occurring. Such was the case in South America when exaggerated fear of carcinogenic by-products from the water disinfection process caused a reduction of the use of chlorine, exacerbating the outbreak of cholera.

CDC SURVEILLANCE PROGRAM

Effective surveillance is key to tracking progress toward these goals. Such surveillance provides policy makers and health professionals with the basis for developing, implementing, and evaluating control policies that will lead to a healthier United States in the new millennium.

From current epidemiologic data, we can conclude that our most important foodborne hazards are microbial, primarily Salmonella, Campylobacter, Listeria, and E. coli 0157.H7. The Public Health Service has included foodborne disease risk reduction in the national health promotion and disease prevention objectives of Healthy People 2000. These objectives

include reductions in the numbers of foodborne infections with Salmonella, Campylobacter, Listeria, E. coli 0157.H7, and Hepatitis A virus, and reductions in the number of egg-associated outbreaks of Salmonella enteritidis infections.

In addition to the aforementioned microorganisms, Clostridium perfringens and Staplhylococcus aureus remain troublesome, particularly in the area of food service, and C. botulinum has begun to show up in such unlikely foods as hazelnut yogurt, salsa, and mishandled cheese spread. Meat and poultry products remain important sources of foodborne disease. These products become contaminated during slaughter and processing, and, when they are undercooked or mishandled, can lead to disease. While CDC's data suggest that foods of animal origin are more often associated with infectious foodborne disease than are other foods, other vehicles also transmit these infections. Our data also suggest that even though most foodborne diseases could be controlled by careful attention to safe food handling practices in the kitchen, they are not; consequently, risk reductions at every point from farm to table are needed to control foodborne disease.

CDC's experience with newly emerging foodborne pathogens, well recognized pathogens appearing in new foods, and foodborne illnesses in immuno-compromised consumers suggests that foodborne disease is an ever changing public health challenge--

a problem of emerging infectious disease. In partnership with representatives from state health departments, other federal agencies, medical and public health professional associations, and international organizations, CDC has developed a strategic plan entitled "Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States." The plan emphasizes surveillance, applied research, prevention and control, and public health infrastructure. I would like to submit a copy of the Executive Summary of this plan for the record.

Some of the high priority implementation goals of the plan are: (1) strategies for population-based investigations to conduct focused prevention projects that emphasize emerging foodborne infectious diseases; (2) prevention effectiveness investigations to assess the impact of food preparation guidelines on the incidence of foodborne infections such as E. coli 0157:H7 and Salmonella enteritidis; (3) developing of additional means to deliver laboratory and public health information for informing health professionals about emerging infections; and (4) providing training in diagnostic evaluation and testing for laboratory personnel and training in public health approaches to diagnosis and molecular epidemiology.

The CDC prevention strategy is based upon the premise that it is far less costly, in both human suffering and economic terms,

to anticipate and prevent foodborne infectious diseases than to react with expensive treatment or containment measures to unanticipated public health crises. Investments in surveillance, laboratory research and training, epidemiologic investigations, and integration with prevention and control efforts will prepare us to respond to emerging infectious disease threats and to lessen their impact.

FDA STRATEGY

Now I would like to turn to FDA's regulatory strategy, which has, over the years, enhanced the safety of the food supply. I will offer two specific examples:

- HACCP-based low-acid canned food regulations, established in 1973, today serve as a template for safety evaluation of emerging technologies such as aseptic processing of shelf-stable foods and ohmic heating of foods which may be vehicles for botulism if not properly processed.

- Various regulations and cooperative industry programs have been implemented to reduce the lead level of the food supply, enhancing the health of neonates and young children. In 1990, we estimated that on average 16% of a 2-year old's daily lead intake comes from food. 1991 DHHS data indicate that there were

250,000 children under 6 years of age suffering from childhood lead poisoning (blood lead levels ≥ 25ug/dL). It is estimated that preventing blood lead levels from rising above 24 ug/Dl yields potential savings of $1,300 per child in avoided medical costs and $3,331 per child in avoided special education costs that would otherwise be required by individuals suffering from lead poisoning. These savings go hand-in-hand with enhanced productivity and quality of life for young children.

Although the current food safety assurance program has generally functioned effectively, it is now facing new stresses and challenges. Here are just a few examples:

- New food processing and packaging technologies such as use of modified atmosphere to prolong the shelf-life and maintain the quality of vegetables, may enable anaerobic organisms, including human pathogens, to proliferate.
- The food supply has become more global. For example, now about 135 different countries supply seafood to the U.S.
- More food is consumed away from home. Nearly 43% of all food dollars are spent eating out.
- We have been faced with outbreaks of illness caused

by microorganisms that we didn't know were human pathogens (the first E. coli O157:H7 human outbreak was 1982) or by pathogens in foods we did not expect (C. botulinum in baked potatoes).

- We are becoming aware that low levels of certain chemicals like lead may be associated with increased risk to some groups and may involve symptoms we have not previously considered.
- Our population is older and contains many more individuals who are immune compromised because of disease or medical therapy than ever before.
- We are faced with the realities of environmental pollution in some areas which we historically rely on to supply food.

At the core of FDA's food safety program is its inspectional strategy. The current strategy, with its emphasis on periodic visual inspection of food facilities, supplemented with end product testing, was designed to control the problems that were known to exist when the FD&C Act was modernized in 1938. This approach was effective for its time but it is relatively resource intensive and has been criticized as being "inefficient" in today's world. Inspections can determine the adequacy of conditions in a food plant at the time of the inspection, but not whether the company is operating reliably and consistently, over the long term, to produce safe food.

Furthermore, the current system of regulatory controls are reactive, not preventive. That is, the system generally relies on detecting and correcting problems after they occur, rather than preventing them in the first place. Only in certain limited areas, such as low-acid canned foods, are mandated preventive controls currently in place.

FDA believes that it is time to consider improvements in the system and adopt a Hazard Analysis Critical Control Point (HACCP) approach to food safety. Such a change has been endorsed by such authoritative organizations as the National Academy of Sciences (NAS), the Codex Alimentarius Commission and the National Advisory Committee on the Microbiological Criteria for Foods (NACMCF).

As described by the National Advisory Committee, HACCP has seven basic steps. It begins with an in depth analysis of potential hazards, followed by identification of points in the processing operation (critical control points) where the failure to control the hazard is likely to result in illness or injury to the consumer. Steps three and four are the establishment of critical limits associated with each identified critical control point and delineation of procedures to monitor the limits. The firm identifies corrective action procedures to be taken when monitoring indicates that a critical limit has been exceeded. Then, an effective

recordkeeping system must be in place to document the HACCP system. Finally, the HACCP system should be verified to assure that it is functioning properly.

On January 28th of this year, FDA proposed new regulations to establish mandatory preventive controls, that is HACCP, to ensure the safety of seafood products sold commercially in the United States and exported abroad. FDA proposed that domestic and foreign processors and importers adopt HACCP controls to prevent the occurrence of identified hazards (microbiological, chemical and physical) that could affect the safety of these seafood products. The comment period for this proposal will close on May 31. Work will begin immediately to analyze and evaluate the comments and publish a final rule. FDA has proposed an effective date for implementation one year after publication of the final rule.

HACCP takes on even more importance with globalization of the food supply and the need for a consistent system for assuring trading partners of the safety of imported products. The U.S. is importing more food, often in processed rather than raw form, than ever before. In the early 1970's, all imported products regulated by FDA numbered approximately 500,000 formal entries (i.e., those valued at $1250 or more). In 1992, 1,117,000 food products alone entered. Likewise, the U.S. exports are increasing yearly. Safety standards have always

varied from one country to another, posing intentional trade barriers in some cases and causing at least import problems in others. However, the rapid move toward a global marketplace makes harmonization of food safety standards and regulations essential to free trade. The U.S., like all other countries, must be prepared to demonstrate that American products introduced into international commerce meet high standards of quality and safety. Industry use of HACCP procedures is one way of accomplishing this. In fact, there is a move within the European Union and the World Health Organization to incorporate the HACCP system into food safety standards and directives.

Because we believe that the future of food safety is with the HACCP approach, we have begun exploring ways to extend HACCP beyond seafood. We have begun to build a consensus within other parts of the regulated food industry itself. After all, it is the industry's legal obligation to produce safe food. The government's regulatory role is to oversee that obligation.

HACCP is a new way to carry out traditional Agency duties. With implementation of the HACCP concept, FDA has stepped back and taken a broader view of food safety. Some people feel that food safety is, and rightfully should be, confined to the production and processing environment, and the only thing that will improve upon the current system is stronger enforcement

and increased regulation. While I do not wish to downplay the importance of regulatory controls and the enforcement of those regulations, I think it is no longer practical to view food safety solely within this framework. In fact, I believe that stepping back and taking a careful look at the big picture is part of the message that comes through in the Vice President's Report "Reinventing Government."

In stepping back and observing, it is apparent that FDA must develop ways to do more with less. This applies not just to FDA, but to other federal and state agencies and industry. FDA has begun to look into other areas where we might make better use of our resources. The way to ensure food safety is to work better by working together, pooling resources where we can. The way we can work smarter is to take every advantage of existing expertise.

FDA's new model Food Code embodies this new "better, smarter" philosophy. This document, published in January of 1994, is an amalgamation of the best scientific thinking of public health professionals from all segments of the food safety community. The Food Code provides the most up-to-date advice to the states on assuring food safety in the retail setting. When States adopt the Food Code it will be incorporated into their food protection law to specifically cover retail food facilities. The Food Code includes guidance on public health protection

issues such as cooking times and temperatures for inactivation of pathogens as well as exclusion of ill employees and proper handwashing procedures as barriers to food contamination. The Food Code also incorporates a framework for the application of HACCP at retail.

Another example of the working "better, smarter" philosophy is the way FDA and USDA approach consumer education. It is difficult for FDA and USDA to inform adequately all food service workers and the general American public about the best ways to prevent foodborne disease. For that reason, the agencies are increasing their efforts to work with other public and private sector organizations to ensure that information on proper food handling practices are widely communicated. For example, FDA/USDA have worked successfully with the Food Marketing Institute over the past several years to convey food handling advice to retail food store employees. To encourage additional joint efforts, FDA/USDA conduct quarterly meetings of the Nutrition and Food Safety Education Task Force. This body consists of representatives from trade, professional and consumer organizations.

To facilitate the exchange of information between the numerous organizations that provide education on food handling practices, FDA has for years, through its State Training Lending Library, provided state and local officials access to

training materials on foodborne disease. To augment this effort, FDA/USDA are establishing a Foodborne Illness Education Information Center. The Center is designed to encourage information exchange about education and training programs directed at food service workers and the public and to make it easier for organizations to find partners for education programs. The Information Center is housed in the Food and Nutrition Information Center of USDA's National Agricultural Library. The Center maintains a database of education activities and materials on foodborne disease, operates an electronic bulletin board on foodborne disease education, answer inquires, and refer callers to organization and foodborne disease experts.

FDA/USDA are increasing their dialogue with the thousands of state and local health and regulatory agencies. Because of the large number of agencies to contact, we utilize multiple communication channels. For example, a video teleconference was conducted on September 2, 1993, and May 19, 1994, for state and local officials to interact directly with FDA and USDA experts. The FDA PRIME CONNECTION Electronic Bulletin Board, established in 1992 for state and local officials, is being expanded to include information from USDA. USDA's proposed Safe Food Handling Labeling regulation was disseminated using this bulletin board.

I believe that the time has come to develop new mechanisms to leverage our current resources and to explore additional joint partnerships with the States. If we are to accomplish our mutual goal in public health protection while at the same time avoiding inefficiencies and needless duplication of efforts, it is vital that we look beyond the traditional organizational boundaries.

Consistent planning, training and utilization of resources for both FDA and State investigation and laboratory personnel is a key to achieving a truly effective national food safety program.

One success story that we might build upon in the area of Federal - State partnerships comes from our recent experiences in training accompanying the implementation of the Nutrition Labeling and Education Act of 1990 (NLEA). Historically, training has been provided by agencies for their own staff. Selected standardized courses have been offered by FDA to States. While these have been excellent courses, they have been limited in scope, subject matter and availability. With NLEA, we have taken a "train the trainer" approach. In essence, we have combined our respective resources and expanded the scope of the effort from the local or regional level to the national level. Resource conservation is only one advantage that is anticipated. We are looking forward to greater

uniformity in the interpretation and application of the NLEA requirements. The point is that this concept can be expanded to other training programs where consistency and uniformity are required, such as in implementation of HACCP programs.

We are all very much aware of the debate that has surrounded new programs that are designed to facilitate collaborative efforts particularly when those collaborations are entered into by parties that some perceive to have missions that are at some level at odds with one another. Some individuals are of the opinion that FDA must remain far removed from the industry. While this view is easily understandable, I believe that there are opportunities for collaboration, opportunities to work together and learn from each other.

In fact, the National Center for Food Safety and Technology (NCFST) is a cooperative government/ academia/industry research endeavor that includes the Illinois Institute of Technology, the IIT Research Institute, the University of Illinois at Urbana-Champaign Food Science Department, FDA and the food related industries. While the NCFST is relatively new we are very pleased with its operation.

Cooperative research endeavors at the NCFST are giving FDA scientists access to resources and providing them with the opportunity to develop essential expertise which would

otherwise not have been attainable by FDA alone. Further, it has provided the Agency with insight into technological trends in the industry. Likewise, industry and academic participants have gained a far better understanding of the Agency and its activities. The work at the NCFST has made a significant contribution to the safety of our food supply. Food processing and packaging research, particularly conducted within the cooperative infrastructure at the Center, builds a strong base of safety expertise and knowledge available to the food science community at large. From this foundation, industry is able to develop technologically advanced products meeting contemporary dietary needs; academia is building food science and technology programs which integrate safety with product and process development; and regulatory agencies are molding proactive, forward looking, food safety strategies. The cooperative environment at the NCFST has created a neutral ground where safety issues are discussed more openly and where strategies geared to designing realistic safety and consumer information programs are formulated.

Implementation of HACCP for seafood and other foods, offers opportunities for several agencies and the states to work together better and smarter. Formation of Federal/State partnerships in which a wide range of resources are shared, such as scientific expertise, equipment, data, and training capabilities, would strengthen regulatory programs and

communications between State and Federal agencies. This is a concept that has been building over the past few years as it became apparent that resources were not going to keep up with the challenges of new technologies and new products entering the marketplace. Partnerships of this type could facilitate more thorough routine regulatory work at the state level, enabling FDA to direct its efforts toward training state personnel and concentrating efforts on high priority food safety issues. By minimizing duplicative efforts in this way, the needs and responsibilities of both States and Federal agencies would be met with the most efficient use of resources. Interagency communication fostered by these relationships would lead to more indepth knowledge about food safety problems, more rapid identification of emerging problems, and most importantly, the application of consistent public health policy across Federal and State lines.

These types of mechanisms for sharing resources have enormous potential benefits for regulatory agencies, industry, and the consumer. Costs associated with ensuring the safety of the food supply can be reduced or at least held steady. Sharing of data and information through more effective communication lines will foster rapid recognition of emerging public health problems and resources can be redirected to their resolution before they become crises. Likewise, trends in the use of new technologies which may have food safety implications can be

pinpointed early. This will give agencies the opportunity to evaluate the technology and its effects on food safety. Thus, the consumer can be assured that only safe products appear on grocery shelves and that the products of safe new technologies are not unnecessarily delayed.

As I have suggested, we are very pleased with the ongoing work at the National Center for Food Safety and Technology and look forward to its future successes. I am also optimistic that the mutual cooperative and collaborative environment can be extended to allowing all of us in the food safety community to make better use of resources and allow the increased levels of food safety.

Conclusion

In summary, the goal of a strong, effective food safety program is public health. While implementation of HACCP will help meet today's public health challenges, the combination of advancing technology, changing consumer demands, and the advent of a global marketplace continues to exert pressure for further change. Increasing resource demands define the need for increased cooperation among public health agencies - federal, State, and international - industry, consumers, and other groups to strengthen food safety programs and direct them to the future.

This concludes my testimony. My colleagues and I would be pleased to respond to your questions.

Mr. TOWNS. Let me just sort of begin. You made a statement, I want to make certain I understand what you are saying. You are saying that more inspections and more inspectors was not the solution in total, what we need to do is step back and take a look at the bigger picture. What do you mean by that?

Dr. SHANK. I am saying that to face today's challenges in food safety I think we need to adopt the HACCP approach to food safety.

Mr. TOWNS. Will FDA require preapproval of the HACCP plan?

Dr. SHANK. We now have a proposal that is out for comments. This is one of the areas that we will be evaluating as we receive our comments.

Mr. TOWNS. Is that yes?

Dr. SHANK. Let me assure you that the traditional inspection program will not be replaced until we have approved a HACCP plan.

Mr. TOWNS. So that is a yes?

Dr. SHANK. That is correct.

Mr. TOWNS. OK. So HACCP plans, I guess, and the monitoring records, will be reviewed by the FDA at the time of an onsite inspection?

Dr. SHANK. In order to have an effective HACCP program there must be the provision of records at least for the critical control points. That would be a very important part of our strategy, yes, sir.

Mr. TOWNS. That is a yes. How will FDA inspectors verify that HACCP is working? Exactly what will FDA inspectors inspect, that is what I am really asking?

Dr. SHANK. We will look at each food processing operation from beginning to end at that particular manufacturing firm. Let's say, from the specifications for incoming ingredients to the requirements for the outgoing ingredients. We will identify those critical control points or those aspects of the process where public health or other safety concerns might arise, and we will evaluate the firms plans and actual critical control points very carefully to assure effective safety limits have been defined and controlled.

Mr. TOWNS. Right. What is the National Advisory Committee for Microbiological Criteria for Foods?

Dr. SHANK. This is an advisory committee that is established under the authority of the USDA; however, FDA has been a very active participant from the beginning. This group is made up of food science professionals, professionals also from industry, primarily academia. They have advised us on such areas as a HACCP program for the future.

Mr. TOWNS. According to that committee, FDA's proposed seafood HACCP regulations mistakenly excluded verification procedures. Does FDA plan to correct this major deficiency?

Dr. SHANK. Let me refer that question to my colleague, Mr. Billy, please.

Mr. BILLY. FDA did not ignore the recommendation of the National Advisory Committee in this regard. However, we did choose to take a different approach. Instead of asking each firm individually to develop a corrective action plan, depending on what type of operation it has, we have proposed and spelled out the require-

ments in regulation that they must meet, to identify where corrective actions are needed, what types are needed, and then to document all of that in records that would be available to us. So we have just chosen a different way of getting to the same end point.

Mr. TOWNS. Suppose they refuse to cooperate?

Mr. BILLY. The regulation will mandate it.

Mr. TOWNS. How many seafood inspectors does FDA currently have?

Dr. SHANK. We have approximately 508 FTEs committed to seafood programs. FTEs is a bureaucratic term that means we expended time equivalent to 508 positions for seafood inspection.

Mr. TOWNS. 508?

Dr. SHANK. That is correct.

Mr. TOWNS. Will FDA seafood HACCP regulations require more resources to implement, specifically to verify HACCP plans?

Dr. SHANK. We estimate that during the initial HACCP inspection there will be an increased time requirement. It will take more time during that initial inspection. However, because of the firm's HACCP program and availability of data, inspections after the initial ones should take less time than what is currently required.

Mr. TOWNS. How many high-risk domestic seafood establishments are there?

Mr. BILLY. We estimate that there are 1,000.

Mr. TOWNS. 1,000. How many low risk?

Mr. BILLY. About 5,000, a little less than that.

Mr. TOWNS. How many verification inspections of high-risk seafood establishments does FDA plan to conduct in the first year of HACCP?

Mr. BILLY. Depends on how the final rule comes out in terms of what the final requirements are, that is the final rule could vary somewhat from what we have proposed, and some of those variations could affect our current plan. Assuming it would go the way it is proposed, we would anticipate being able to carry out approximately 1,000 inspections of establishments in the first year in which HACCP is mandated in the industry.

Mr. TOWNS. All right. If it goes the way it is proposed in the first year, how many would you be able to do in the second year?

Mr. BILLY. It would be about the same number because we would still be completing the review and evaluation of the plans and their implementation in the plants.

Mr. TOWNS. How many verification inspections of low-risk seafood establishments does FDA plan to conduct in the first year of HACCP?

Mr. BILLY. The 1,000 inspections would include mostly high-risk plants but some low-risk operations in both years. We would do about 700 of the high-risk plants the first year and the remaining 300 the second year, to cover all the high-risk plants. The remainder of the 1,000 inspections over the first 2 years would be the other types of facilities.

Mr. TOWNS. Let me go to my real question. How many years will it take FDA to verify that all seafood establishments have effective HACCP systems?

Mr. BILLY. It will take us approximately 5 years under our existing resources.

Mr. TOWNS. These estimates are based on the assumption that the verification inspections for a seafood establishment will require about how many hours to conduct?

Mr. BILLY. On average 40.

Mr. TOWNS. Do these estimates assume that all inspected HACCP plans are adequate?

Mr. BILLY. No, it does not. To deal with these instances, we are leaving some flexibility in the 1,000 inspections that we have planned. Where we find that a firm has not properly established a HACCP plan or implemented it, then we would intend to take appropriate followup action which could include visiting the establishment again very quickly once we have indicated that changes are required.

Mr. TOWNS. I think this one probably only requires a yes or no. Has FDA conducted a pilot HACCP study for the seafood industry?

Mr. BILLY. Yes.

Mr. TOWNS. What percentage of HACCP plans were found to be inadequate through FDA's verification inspection?

Mr. BILLY. I don't know the answer to that. I would have to provide it for the record.

Mr. TOWNS. Does anybody know?

Dr. SHANK. Mr. Chairman, we would have to get that information for you.

Mr. TOWNS. Without objection we will hold the record open for it.

Dr. SHANK. Yes, thank you.

[The information follows:]

Eight plants participated in the FDA/NOAA seafood HACCP pilot for domestic processors. The pilot involved presubmission of HACCP plans by the participants to FDA/NOAA, followed by a paper review of the plans by FDA/NOAA for general adequacy and on-site inspections to evaluate how well the plans matched actual plant conditions. The operational phase of the pilot, during which the plants engaged in HACCP operations on the basis of their plans, did not occur until the plans were satisfactory to FDA/NOAA. The initial HACCP plans developed by the participants were found to be of mixed quality, but by operational phase of the pilot, all were satisfactory.

Mr. TOWNS. At this time let me yield to my colleague Mr. Schiff from the great State of New Mexico.

Mr. SCHIFF. Thank you, Mr. Chairman.

The first thing I would like to ask, Dr. Shank, is something that is not exactly the subject of this hearing. It is something I have run into back with my constituency concerning the FDA, and I don't want to bring up any matter by surprise, so if you are not familiar with this matter I would welcome at a future time your contacting me by letter or however you see appropriate, but this deals with the import of food and pharmaceuticals from other countries as they come through our borders.

I have constituents who buy pharmaceuticals in Europe, for example, where they are legal in Europe, and they may or may not be yet registered and approved by the FDA in this country, and they inform me that the FDA gives its enforcement power on allowing or not allowing something in this country to the Customs Department in that area, and they say, this is what they are telling me now, I cannot tell you I am a witness to this, they tell me the Customs Department is entirely arbitrary in enforcing FDA guide-

lines, that it almost depends on which Customs agent you happen to run into at a particular moment as to whether a particular pharmaceutical will or will not be admitted to this country. Is this an area that you can discuss right now?

Dr. SHANK. The jurisdiction responsibilities for pharmaceuticals is in a center that is different than mine, and I would very much like to take your question and provide the answer through a letter or as you desire.

Generally speaking, we have a very good relationship with the Customs officials and it is a joint responsibility overall with some individual responsibilities on either side, but we would be glad to get you the answer.

Mr. SCHIFF. I would welcome your forwarding my remarks to the appropriate official at FDA so that I can respond to my constituents.

Dr. SHANK. We will do that.

Mr. SCHIFF. Thank you.

On the issue of food safety inspection itself, did I hear you correctly estimate that 9,000 people die a year in the United States from contaminated food? Is that your estimate?

Dr. SHANK. That is an estimate. I would point out that the data are not as solid as we would like. Some argue that that number is too low, but that is the best estimate that we can come forward with at this point.

Mr. SCHIFF. But even the figure 9,000 a year strikes me as a great deal higher than I would ever have imagined if someone would have just asked me if I were walking down the street how many people may die as a result of food contamination. I mean, that suggests—I realize it is not as many people as those who die in auto accidents, but it just strikes me as when combined with the serious injuries that must be present but not result in death a rather significant problem existing right now.

Dr. SHANK. Let me yield to my colleague from CDC, Dr. Blake. CDC is the primary agency that deals with these types of estimates.

Mr. SCHIFF. Doctor.

Dr. BLAKE. That estimate was put together back in the mid 1980's, and the reason the number is so high is that the vast majority of cases of foodborne disease are not associated with a known outbreak. The outbreaks that know about and investigate form a very small proportion of the actual number of foodborne disease cases because when foodborne disease occurs in two or three or four people as a result of eating a food, usually they will not associate it with that food, and it will never come to the attention of the health authorities. For example, with salmonella we have 45,000 cases who are actually cultured and brought to our attention every year, but the number who are part of recognized outbreaks is much, much smaller than that.

Mr. SCHIFF. So in other words it is kind of individual cases that occur around the country with death resulting perhaps by factors that include, as I think you indicated, the individual's own constitution to resist this contamination?

Dr. BLAKE. Right. It is extrapolating from the data that we know about to the number that we think is actually occurring.

Mr. SCHIFF. But the point is if we were to lose that number of people in one catastrophe I think this whole subject would have a higher level of public attention than I think it now has, would you agree with that?

Dr. BLAKE. Yes. I think the fact that the vast majority of cases of foodborne disease occur as sporadic cases which are not recognized as part of outbreaks keeps it from being brought to the attention of the public as much as it might be if it occurred as one enormous outbreak.

Mr. SCHIFF. Exactly. One other thing I would like to ask about. The overriding subject of this hearing and these hearings is to deal with the Vice President's proposal in reinventing government to consolidate USDA's Food Safety and Inspection Service into the Food and Drug Administration. What I would like and I will turn to you, Dr. Shank, first on this, does the Food and Drug Administration support that idea?

Dr. SHANK. I am not prepared to give you the agency's position today pertaining to the Vice President's recommendation. I can say, however, that one part of his recommendation was for us to improve upon the way we deal with food safety. We have been discussing this morning our efforts in seafood to move to a preventive system, to the HACCP system. We are doing that. USDA is considering ways in which they might make similar changes, so to the extent that the Vice President's report says let's do a better job, we are moving in that direction with the resources that we have available to us. I am not at liberty to talk, I do not know the agency's position relative to the organizational placement.

Mr. SCHIFF. Well, Mr. Chairman, first of all, I understand Dr. Shank has a defined area of responsibilities, and I do not mean this directed at Dr. Shank personally or any individual with him, but if I understand, if I have looked at the next list of witnesses correctly there is no other representative of the administration testifying here today, so—and I assume that the Office of the Vice President was invited to attend here today, Mr. Chairman.

Mr. TOWNS. That is correct.

Mr. SCHIFF. I want to say particularly because I have a certain sympathy for this recommendation, as I have already indicated, I am greatly disappointed, first, that the Vice President's office would not send a representative to discuss a proposal that they have made that we are considering here today, and, second, again with no offense to Dr. Shank or any panelist, that the Food and Drug Administration would not send anyone in the appropriate policymaking position to answer the question about how they feel about that recommendation. I think that is a great loss to what could have been accomplished at this hearing. Nevertheless, I assure you I thank Dr. Shank and your colleagues for the testimony you have provided. I yield back, Mr. Chairman.

Mr. TOWNS. At this time I yield to Congressman Portman.

Mr. PORTMAN. Thank you, Mr. Chairman. I would like to echo many of the comments of my colleague from New Mexico with regard to consolidation. That was really as I understood it, the focus of the hearing. We had a good hearing earlier in this subcommittee where we talked to the Department of Agriculture about its food

safety programs with an effort I think on our part to understand better what their capabilities might be.

This hearing, as I understood it, was in part to look closer at the FDA's programs, seafood inspection, the HACCP program, and so on to see whether in fact the recommendation of the Vice President's National Performance Review was appropriate, specifically that FDA would have the capability of taking on additional responsibility, and my questions were really directed toward that. I would hope, Dr. Shank, that perhaps you could answer a couple of questions in this regard, notwithstanding your response to Mr. Schiff.

Specifically, how long do you think it would take if the National Performance Review recommendations were followed, and that again is very specific. It says that FDA should handle food safety, that the inspection service under USDA should be eliminated, it should be consolidated under FDA. What would be the time period, what would be the transition period that you would think that would take?

Dr. SHANK. I think that that type of a change would be very complex. There would, in order for us to achieve our maximum efficiencies, probably have to be some changes in legislation because just to put the two organizations together would not solve some of the basic problems. Beyond that, I am not in a position to lay out a blueprint or give you a timeframe as to how quick that could be accomplished. Obviously, it could foreseeably be accomplished relatively quickly if that was the desire of the administration. On the other hand, it may be protracted if you take care of the legal obligations first. I am not knowledgeable and have not been a part of any planning, so I could not give you a learned answer on that question.

Mr. PORTMAN. The other question, I don't expect you to have an answer today, but what would be the cost of such a transition, a cost to the Federal Government generally, of course specifically to FDA, what would be the net cost of such a consolidation?

Let me ask a followup question to your previous answer. Is there anyone at FDA or for that matter to your knowledge anybody at HHS or at USDA or in fact in the administration generally who is undertaking such an analysis of what this sort of a transition timeframe would be and what the cost might be?

Dr. SHANK. We are very actively pursuing the first part of the Vice President's initiative, and that is to do a better job on the food safety area. We are currently developing a strategic plan for FDA which the food program is a very important component. I am very much aware that these types of discussions are being held at the most senior levels of our department.

As far as organizational changes, I am not aware of those. I am not in a position to tell you about those discussions because I don't know if they are occurring and I have not been a part of them.

Mr. PORTMAN. So your answer would be that you are not aware of any feasibility studies or any analysis of the transition costs or the timeframe?

Dr. SHANK. That is correct.

Mr. PORTMAN. OK. Are there any other panelists who would wish to respond to this question? No? All right.

Mr. Chairman, I guess I have no further questions, except just a comment, and that is to say that I would hope that this proposal by the National Performance Review was a serious one. I think as my colleagues have mentioned, it merits further discussion. I am generally supportive of the notion of consolidation if it saves costs as the GAO tells us, and I think as the Vice President's office tells us, and leads to a more effective food safety program in this country, and I would hope the administration takes it seriously as well. Thank you, Mr. Chairman.

Mr. TOWNS. Thank you, Congressman Portman.

Let me just raise this question. Last night we received several documents, that show FDA has deliberately asked for fewer resources than it needs to successfully operate the HACCP program. This probably means needless illnesses and of course in some instances death. If you need additional resources, Dr. Shank why don't you ask for them?

Dr. SHANK. Mr. Chairman, we received very definitive guidelines as to what our budget request could do, what our budget request should be. We are continuing to establish priorities and to adjust priorities as we see fit, given the constraints which we have to work under.

Mr. TOWNS. Well, I think we can make the case because if people are getting sick and going to the hospital and that is going to cost money, and we are talking about health care reform. This might be a good time for you to raise this issue.

Dr. SHANK. Mr. Chairman, we are very much aware of the debt that hangs over our Nation and the difficult situation we have with the Federal budget, but if we were to receive additional resources, we could, we believe, be more efficient and provide more consumer protection. Examples of what we would do are to implement our HACCP initiatives on a more expedient basis and to strengthen our partnerships with our State colleagues.

Mr. TOWNS. Well, maybe you have to make the case that we were able to make in some other areas where they were closing the poison control centers at the same time we are trying to reform health care. Sometimes some of these things just don't make sense. If you are going to close something that is going to make you spend more on the other end, I think that that is something that needs to be questioned. I think that the timing of your request might not be any better because the country is talking about health care and when you talk about food safety, you are talking about saving lives here. This is what we are talking about. So I think that you might need to take another look and push a little more for resources because now is the time to do it, I would say.

Let me move on. Do you agree with the 1991 National Academy of Science's report that the major risk of disease from seafood is associated with the consumption of raw shellfish, oysters, clams, and mussels?

Dr. SHANK. Yes, sir.

Mr. TOWNS. Has FDA set limits for the bacterium vibrio vulnificus in raw shellfish?

Dr. SHANK. I yield to Mr. Billy, please.

Mr. BILLY. No, sir. Although we are involved in extensive research to try to determine what dose causes illness, we have not

yet been able to pinpoint it. To further that effort, though, we are hosting and sponsoring a workshop of experts in this area from all over the country in mid June to explore that area further and determine whether or not sufficient data and information exists to set a specific limit. Our intent is to do so as soon as we are able to, based on sound, scientific data.

Mr. TOWNS. Does FDA regularly sample and test raw oysters to determine the extent of contamination with vibrio vulnificus?

Mr. BILLY. No, sir. Shellfish safety is handled under a cooperative program between FDA and the States. The States basically carry out the regulatory activities of monitoring the growing waters, testing the product where it is appropriate, and inspecting the shucking houses and other processing operations that handle raw shellfish. We audit the States to verify that they carry out those types of activities.

We also conduct research and we have collected some data on the occurrence of v. vulnificus in oysters from different harvesting areas and at different times of the year. We are building a data base that would provide the framework for some additional controls in terms of harvesting.

Mr. TOWNS. I think that really points out the statement made by Congressman Portman, it is so important because if you have someone doing business in more than one State, this could really be a problem. Anyway, I think it just points out that consolidation is needed.

The clerk will now play an excerpt from a TV news magazine show that aired last February:

Unidentified SPEAKER. Millions on all kinds of foodstuffs. Cooking destroys it.

Dr. KESSLER. I don't think that you use the fact that you can cook bacteria out, I mean, in the end as a substitute for good quality control.

John QUINONES. Would you eat raw fish?

Dr. KESSLER. Would I eat raw fish? No. I think that—I am not going to sit here and tell people not to—if you are asking me personally whether I would eat raw shellfish, the answer is no. Would I allow members of my family to eat raw shellfish? I advise against it.

Diane SAWYER. So what can you do?

Mr. TOWNS. Do any of you eat raw oysters?

Mr. BILLY. I do.

Mr. TOWNS. You do? Anybody else? I have here a bag of raw oysters that I purchased this morning from a local retailer. The clerk claimed that the oysters were from Texas, but there were no tags or warning signs posted on it. Can I as a consumer be certain that these oysters are not contaminated with vibrio vulnificus? Can I?

Mr. BILLY. No, sir, you cannot.

Mr. TOWNS. USDA now requires a safe handling and cooking label on raw meat and poultry. Why doesn't FDA require a similar warning on other raw animal products such as raw oysters?

Dr. SHANK. Mr. Chairman, we are fully aware of what USDA is doing, and we have taken a number of initiatives in that area. There are two ways that we can handle the problem with vibrio vulnificus in raw oysters. We can provide educational tools or we can provide point-of-purchase labeling. We have not decided which way we are going to go. However, that does not mean that we do not have an active program.

Since 1992, we have made wide distributions to health care providers and to consumers about the importance of cooking oysters. Our position is that anyone who has a compromised immune system should eat cooked oysters and not eat raw oysters. Some of that information that we have provided went directly to the health care deliverers. The vast majority of the people who have the diseases to which there would be severe consequences and possibly death from oysters, are being treated by these health care providers. It is through that mechanism that we are trying to educate the people.

In our proposal for HACCP that was issued for seafood, we have raised the issue and requested comments on whether or not we should provide point-of-purchase labeling for raw molluscan shellfish. I could go on. There are other initiatives that we have undertaken. The point being we are giving this very serious consideration, and we will be making a decision as to what steps are appropriate in the future and what additional steps that we need to take. We will be making that decision in the near future.

Mr. TOWNS. Well, I don't want to deal with this point too long, but I would have to ask again why FDA does not require a warning label on raw shellfish because many people are not aware that they are at risk. I think that the only thing that really makes sense to me is that FDA should require warning labels.

Dr. SHANK. There are some very valid arguments for having point-of-purchase labeling. We are continuing to pursue that along with our educational efforts.

Mr. TOWNS. Let me ask the Members do they have any other questions of the panel? Let me thank——

Dr. SHANK. Mr. Chairman, if I could, early during my testimony when you were asking for yes and no answers and I was asked about preapproval of all HACCP plans, my counsel pointed out that we are in the process of public rulemaking now; we are soliciting comments. The way I responded was the best approach as we see it today. The final outcome with the final regulations may be slightly different based upon the comment.

Mr. TOWNS. Let the record reflect the correction. Thank you.

I thank all of the members of the panel for your testimony. I look forward to working with you to come up with something that is going to help save lives. Thank you very, very much.

I would like to call the fourth and final panel, Juanita Duggan, Sherwin Gardner, and Lee Weddig. May I ask you to please stand and raise your right hands.

[Witnesses sworn.]

Mr. TOWNS. Let the record show that the witnesses answered in the affirmative.

Let me thank you very much for taking time from your busy schedules to come and to be with us today. Let me remind the witnesses that your entire statement will be included in the record. If you would summarize within 5 minutes that will allow the members to raise questions with you which I think might make it possible for us to even cover more. Why don't we begin with you, Ms. Duggan.

STATEMENT OF JUANITA DUGGAN, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION

Ms. DUGGAN. Thank you, Mr. Chairman. I am Juanita Duggan, senior vice president of government affairs for the National Food Processors Association, and I will be happy to try to summarize within 5 minutes.

NFPA is a science-based association with three state-of-the-art food science laboratories staffed by more than 80 scientists. We very much appreciate the opportunity to testify at this hearing on reinventing Federal food safety systems.

We believe the Food and Drug Administration has done a good job of working with industry to ensure the safety of the Nation's food supply, but it is important to note that the responsibility for producing safe food rests with food companies, while FDA's responsibility lies in assuring that the food company has met its obligations. We think that is an important distinction to make. Industries always carried this burden and looking at the record has done well.

Food safety problems related to processing and production are, in fact, uncommon. FDA and the U.S. Department of Agriculture are considering the adoption of hazard analysis critical control point programs for the food industry. My comments today are equally valid for both FDA and USDA processes.

HACCP is probably one of the single most important actions that the Federal Government can take to actually improve food safety because it is proactive rather than reactive, and it is science based. HACCP has the potential to bring about fundamental shifts in the way the food industry provides assurances of safe production practices and how regulatory agencies will verify those practices. It can change the approach from one that corrects problems after they develop to one that prevents them.

At this point we believe that HACCP should be voluntary for most of the food industry, while acknowledging the fact that mandatory HACCP may be appropriate for some products if a significant safety risk has been scientifically determined.

It is important to note that that is the way the seafood HACCP rule has developed, and we think that it is important to point to the experience the food industry has had with the low acid canned food regulations that are in fact HACCP programs in their own right and were in fact initiated by the National Food Processors Association in the 1970's.

We believe that the proposed rule for HACCP and the seafood industry is headed in the right direction, although parts of the proposal do not specifically address food safety, which will cause problems for both the food industry and the regulators.

NFPA believes it is imperative that only food safety factors be included in HACCP programs. FDA does not have the authority or the resources to consider quality control issues along with food safety matters. Industry's resources are also limited and should be focused on the area of greatest importance, producing safe food. Any expansion beyond safety will dilute the HACCP mission and will be counterproductive.

We also are concerned about FDA prior approval of HACCP plans. We know our products and processing lines better than anyone and the regulatory agencies do not have a complete understanding of every product. So we are opposed to prior approval of HACCP plans and believe that would be an unneeded and unnecessary burden for the agencies.

We also have some concern about the records access proposals in the seafood HACCP rule. FDA's records access should be limited to those documents that apply only to HACCP, and again this is the experience we have had with the low acid canned food regulations. Inspectors should have access only to those HACCP records that are essential to verify a HACCP plan.

FDA has raised the possibility that inspectors should have access to non-HACCP related records, such as consumer complaints. Most consumer complaints are not related to health or safety, and should not be part of a records access scheme.

FDA faces imposing responsibilities in the food safety area and HACCP should be able to allow regulators to make better use of finite resources and high technology, but it should not be used to expand FDA's authority.

With regard to funding, several of your witnesses here have talked about the need to adequately fund the FDA, and NFPA strongly supports a level of funding that will enable FDA to perform its food safety mission. We would note, however, that Congress has aggressively expanded the mandates for FDA in the past few years, such as the Nutrition Labeling and Education Act and has considered some new enforcement authorities and tolerance-setting procedures for pesticide residues. We strongly urge that when mandates are expanded, additional funding to fund those mandates be included because it simply stretches the resources.

We would also like to make the point that the imposition of user fees on the regulated industries would be an inappropriate way of providing such agency resources, and that if FDA were to draw its funding from the food industry which it regulates, public confidence in the integrity of the FDA and the safety of the Nation's food supply would be compromised.

NFPA believes that building consumer confidence is a very important mission of the FDA, and the USDA. The Government must use its credibility to educate the public about food safety as well as the safety of innovations that they approve. This is a situation that has reached critical importance with the approval of BST, biotech products, and irradiation.

When the FDA has used a science-based approach to approving the safety of new technology, we believe they should also use their authority to create nationally uniform food and food safety laws, thus keeping a maze of conflicting State and local regulations from emerging. That is precisely what we are now facing with BST and some of the other biotech products.

With regard to your interest in consolidation of food safety functions within a single food agency, we would note that separate food safety regulatory regimes were created based on the fact that there were real differences in the safety issues facing various food products and production lines.

The differences in the safety and inspection needs for these products are great. We believe that moving to a HACCP system is one of the best ways in the short term of creating consistency across the board. We have not seen a convincing argument yet that consolidating all food safety responsibilities in a single food agency would improve food safety per se or necessarily result in government efficiencies. We would note that we saw your article yesterday in Roll Call, Mr. Chairman, and agree with your premise that changing the boxes on the organizational chart does not necessarily save lives, that what is needed is the will to act. We would very much agree with that and hope that we can move forward with promising new technologies now that have real opportunities for food safety improvements.

Consolidation could also, we think, in the short term delay what we have started with HACCP both at the FDA and hopefully what will be started on at USDA very soon, and we would be very concerned if we were to lose the momentum on those new technologies and approaches by virtue of trying to consolidate.

There is also a great deal of discussion about enforcement activity and enforcement authority within the FDA.

I would like to bring to the committee's attention that FDA has a tremendous amount of enforcement authority, and this has been a subject of tremendous debate within the Energy and Commerce Committee over the past few years. They have issued many reports and have attempted in the past to pass legislation, but they have really been unable to make the case that FDA was unable to deal with any significant food safety problem in the marketplace.

There is a potential that maybe import issues could be a real problem, but with regard to the domestic food supply and domestic food processors, there has not been a case made that there is insufficient authority to get products that are injurious out of the marketplace. I would note that FDA does have the ultimate enforcement tool which is absolute criminal liability without knowledge or intent, for personnel in the food industry. They can go to jail for violations, and even trivial violations, of the Food, Drug and Cosmetic Act, so we believe they do have very, very strong enforcement authority and that that has worked very well.

We appreciate the efforts of this committee and your consideration of our views, and I will be happy to answer any questions you may have.

Mr. TOWNS. Thank you very much, Ms. Duggan.

[The prepared statement of Ms. Duggan follows:]

NATIONAL FOOD PROCESSORS ASSOCIATION

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Statement of

Juanita Duggan
Senior Vice President, Government Affairs

National Food Processors Association

Before the

Human Resources and Intergovernmental Relations Subcommittee
of the House Committee on Government Operations

Hearing on

"Reinventing the Federal Food Safety System"

May 25, 1994

Mr. Chairman: I am Juanita Duggan, Senior Vice President of Government Affairs of the National Food Processors Association. NFPA is the nation's largest food trade association, representing the $400 billion food processing industry. Our member companies produce the nation's processed and packaged fruits and vegetables, meat and poultry, seafood, juices and drinks, and specialty products.

NFPA is a science-based association with three state-of-the-art food research laboratories staffed by more than 80 scientists. NFPA's laboratories conduct studies on food safety, nutritional content of food and innovative food processing and packaging technologies designed to achieve optimal safety, wholesomeness and nutritional value of food products. The technical expertise of NFPA is brought to bear in its representation of its member companies in matters of scientific, government and consumer affairs.

NFPA appreciates the opportunity to testify at this hearing on reinventing the federal food safety system.

We believe that the Food and Drug Administration has done a good job of working with the food industry to ensure the safety of the nation's food supply. It is important to note that FDA and the food industry play differing roles in food safety. The responsibility for producing safe food rests with the food company, while FDA's responsibility lies in assuring that the food company has met its obligations.

Inspection procedures and other government food safety programs must not place the burden of safe food assurance on the shoulders of FDA. This is functionally incorrect. Industry has always carried this burden and, looking at the record, has done well. Food safety problems related to production by industry are rare.

FDA is now proposing the adoption of Hazard Analysis Critical Control Point (or HACCP) programs for the food industry. And the U.S. Department of Agriculture has held a Round Table on HACCP in anticipation of issuing a proposed rule on HACCP. Both agencies have demonstrated an admirable openness and willingness to take the food industry's concerns into account and to learn as much as possible about the real world of HACCP. My comments today are equally valid for FDA and USDA food safety efforts.

HACCP has the potential to bring about very basic shifts in the way the food industry provides assurances of safe production practices and how regulatory agencies will verify those practices.

HACCP can tie together the industry's safety systems and government oversight. It can change the approach from one that corrects problems after they develop to one that prevents problems from occurring.

As the food industry's scientific and technical trade association, NFPA naturally is playing a major role in all movements toward HACCP application. Our primary focus is on trying to make HACCP work for the benefit of all parties: the food industry, government and our consumers.

At this point in time, we believe that HACCP should be voluntary for most of the food industry, while acknowledging the fact that mandatory HACCP may be appropriate for some products if a significant safety risk has been scientifically determined.

The words "voluntary" and "mandatory" must not be allowed to polarize various parties on HACCP and must not be used to derail industry and government HACCP efforts.

We believe that FDA's proposed rule on HACCP for the seafood industry is headed in the right direction. However, parts of the proposal do not specifically address food safety, which would cause problems for both the food industry and regulators.

It is imperative that only safety factors be included in HACCP programs. FDA does not have the authority or the resources to consider quality control issues along with food safety matters. Industry's resources also are limited and should be focused on the area of greatest importance: producing safe food. Every HACCP requirement carries with it record-keeping and inspection burdens.

Areas such as detailed sanitation practices belong in the broad category of Good Manufacturing Practices. While vitally important to food production, quality control issues should not be included in HACCP plans unless they directly impact food safety.

NFPA would oppose a requirement for FDA prior approval of HACCP plans. The food industry knows its products and processing lines better than anyone. The regulatory agencies do not have the full understanding of every product and product line in our industry for purposes of preapproving HACCP plans. Prior approval will also place unneeded burdens on agencies whose resources already are stretched.

As I stated earlier, the responsibility for manufacturing safe products rests with each company. The inspection authority's role is to verify that the company is meeting its obligations.

Obviously, the Agencies must be satisfied that company safety systems will protect public health, and inspectors must have the right to review necessary records and confirm that the safety systems are working. However, FDA's records access should be limited to those documents that apply to HACCP. Inspectors should have access only to those HACCP records that are essential to verify that a HACCP plan is being followed.

FDA has raised the possibility that inspectors should have access to consumer complaints as part of HACCP records. NFPA and an industry HACCP coalition will vigorously oppose opening company complaint files to government inspectors. Consumer complaints are just that: complaints. Most are not even related to health or safety issues. They should not be part of the records access scheme.

Verification that the company is producing safe food comes from reviewing records identified in a HACCP plan. A food production line is either in control or it is not, and this alone should be the regulators' point of focus.

FDA faces imposing responsibilities in the food safety area. HACCP should be used to allow regulators to make better use of finite resources. It should not expand FDA's area of authority.

NFPA strongly supports a level of funding that will enable FDA to perform effectively its important food safety mission. However, the imposition of user fees on regulated industry would be an inappropriate means of providing such agency resources. In the area of food safety, as in all areas regulated by FDA, the Agency's integrity must be both real and perceived. If FDA were to draw its funding from the food industry, which it regulates, public confidence in the integrity of FDA and in the safety of the nation's food supply could be seriously undermined.

To reach their full potential, HACCP and other FDA food safety programs should apply at every step of the food chain, from farm to fork: growing, harvesting, processing, distributing and preparing food for consumption.

Applying HACCP to food processing operations is important, but there are many opportunities for perfectly safe products to be contaminated after they have left the plant. Grocers, retailers and restaurants which prepare food products directly on their premises must be considered an integral part of our nation's food safety chain. More must be done to educate food handlers and consumers in the basics of safe food preparation. The data show that most food-borne illness results from mishandling in food service establishments and at home.

HACCP is not the only technological advancement that can enhance our nation's food safety. Other new and important technologies, such as food irradiation or biotechnology, can play a important role in ensuring that U.S. consumers continue to enjoy the world's safest food supply.

We need increased reassurance from the federal agencies that regulate food production about the safety not only of traditional products and production methods but about the safety and importance of new technologies and the resulting food products. FDA and USDA must make decisions based on sound science and not hesitate to defend those decisions in a public forum.

Government must use its credibility to educate the public about the safety of the innovations they approve. Moreover, FDA must use its authority to create nationally uniform food and food safety laws, thus keeping a maze of conflicting state and local regulations from emerging.

Separate food safety regulatory regimes were created based on the fact that there are real differences in the safety issues facing various food products and production lines. The differences in the safety and inspection needs for these products are great.

We have not seen a convincing argument that consolidating all food safety responsibilities in a single agency would improve either food safety or governmental efficiencies. The focus of government safety efforts must be on food safety itself, not on creating new bureaucratic entities which may have difficulty fulfilling the responsibilities now spread among several agencies.

Mr. Chairman, we appreciate the efforts of this Committee and your consideration of our views.

Mr. TOWNS. Mr. Gardner.

STATEMENT OF STEVE ZILLER, VICE PRESIDENT, SCIENTIFIC AND TECHNICAL AFFAIRS, GROCERY MANUFACTURERS OF AMERICA

Mr. ZILLER. Mr. Chairman, members of the committee, I am Steve Ziller, vice president of scientific and technical affairs for Grocery Manufacturers of America. Mr. Gardner is unable to be here this morning because of serving on jury duty across town. I certainly appreciate the opportunity to appear before the committee to present GMA's views on the Federal food safety program.

My statement addresses the four issues specifically requested by the committee. Before discussing these issues, I should like the committee to note that GMA supports a strong and effective FDA. The agency's responsiveness to the issues and its credibility with the American public and the food industry are key components in assuring a safe food supply. Of equal importance is excellence in the agency's scientific capabilities and resources.

To maintain this excellence it is very important that Congress fully support the agency from general revenue. The safety of our food and medicine should be a very top priority and Federal responsibility, and over the years GMA has appeared before the Appropriations Committees and supported full funding of the agency.

At the same time, however, all of us need to do a better job in managing what resources we have to do our jobs. The food industry has embarked on massive efficiency and productivity improvements. We respectfully request all Federal agencies, including FDA, should consider similar actions.

The approvals of food additives, controls of imported foods, and timely completion of regulatory proposals are examples of areas in which FDA must improve. The opportunity to improve agency performance and efficiency is why we are encouraged by the interest in reinventing the Federal food safety system.

In reference to your question one, FDA already has a strong and effective array of enforcement tools ranging from plant inspection to court-ordered product seizures, injunctions, and criminal penalties. The agency also has developed with the cooperation of the regulated industry effective regulations for the assurance of safety, for example in the case of acidified foods or for thermally processed low acid foods. In our view, FDA has sufficient enforcement tools to ensure the safety of the Nation's food supply, if they are applied in the most cost effective and focused manner.

The agency has proposed its mandatory HACCP regulations for seafood under its current authority. These proposed regulations would extend the use of a widely applied industry developed voluntary approach for assuring the production of safe food.

GMA supports the voluntary application of HACCP in the seafood industry with selected mandatory applications where scientifically justified. GMA also supports in principle the application of HACCP to the seafood industry, although the FDA's proposal overreaches in records access, and it is overly prescriptive and does not allow the essential flexibility needed for an appropriate HACCP program.

HACCP should be focused primarily on the serious safety issues. These and other flaws, if not corrected, seriously jeopardize effective HACCP implementation and result in a waste of FDA and industry resources with no offsetting gain in public health protection.

GMA has been cooperating with the agency in developing training programs for FDA inspectors in order to help ensure the agency's inspectors are technically qualified in understanding HACCP techniques.

In addition to its inspection and enforcement responsibilities, FDA is exploring ways to improve effectiveness of its premarketing review responsibilities. This is an area of urgent need of improvement.

GMA also believes that the agency could materially improve its effectiveness in safety reviews by adopting the use of expert scientific advisory committees for evaluating food additive petitions as it now has for new drugs. Failure to address these issues quickly is an enormous disincentive to investments in new food technology to the ultimate detriment of consumers.

In reference to your question two, food safety is the food manufacturer's fundamental responsibility. FDA's inspection activities are inherently well suited to this purpose by focusing on manufacturing activities in implementing systems of quality assurance and control.

FDA's role should be to verify how well these HACCP programs are being carried out by food manufacturers to establish realistic policies, to contribute to the scientific knowledge base about food risk, and to undertake enforcement actions in a timely manner when HACCP programs and their scientific support base are not in compliance with regulations.

The voluntary adoption of an effective food safety approach should be encouraged by the FDA. HACCP is designed to reduce or eliminate foodborne illness by controlling the truly critical safety risks in food processing.

Question three. One of the strongest recommendations of the Edwards committee in its May 1991 report to Health and Human Services Secretary Sullivan was that the FDA must clearly define its overall mission and develop a formal statement of purpose.

Last July, Commissioner Kessler issued a mission statement that has been developed by the agency. It is appended to my statement that was submitted. GMA is in agreement with the Commissioner's mission statement and the principles incorporated within it. It is built around a sound scientific and legal base, clearly understandable regulations, and involvement of public, industry, and all parties. It is certainly applicable to the question raised about the guiding principles of an optimal food safety system.

Question four. GMA believes that for the time being the two agencies, FDA and FSIS, should continue to be separate for several reasons. First, the technologies and constituencies of the regulated sectors are dramatically different and would likely involve an extensive accommodation period which would be highly disruptive to improvements being undertaken separately by both FSIS and FDA at the present time.

Second, the very broad scope of FSIS responsibilities would overwhelm FDA's management systems and detract from its other important work in the area of drugs, biologicals, and medical devices.

Third, submerging a combined operation of the size of FDA and FSIS within the Department of Health and Human Services is not likely to improve its performance because of the multitude of management layers that would exist. Indeed, the food function within FDA would become larger than the entire agency is today, which would suggest that perhaps there could be two agencies, a Drug and Medical Products Administration and a Food Safety Administration, but in our view consolidation of food safety functions within HHS is not practical. The committee should also note that some food safety responsibilities reside with the EPA for establishing pesticide residue safety requirements.

Mr. TOWNS. Mr. Ziller, could you summarize.

Mr. ZILLER. And also some functions of USDA.

In conclusion, food safety is recognized as important and is being actively managed by USDA and FDA. A number of key initiatives and reorganizations have begun, and those efforts should be completed.

With respect to FDA, GMA is eager to work with the appropriate committees of the Congress and FDA to design an approach that would more carefully target general revenues to top food safety priorities, particularly pesticide monitoring, food plant inspections and import inspections at the border. In other areas important to the food industry and consumers, such as approval of new foods and ingredients, GMA urges the FDA to develop more efficient processes to help improve the speed of such reviews.

This completes my prepared statement.

Mr. TOWNS. Thank you very much, Mr. Ziller.

[The prepared statement of Mr. Gardner follows:]

Testimony Presented by
Sherwin Gardner, Consultant
for the
Grocery Manufacturers of America, Inc.
before the
Human Resources and Intergovernmental Relations Subcommittee
of the
House Committee on Government Operations
May 25, 1994

Mr. Chairman, Members of the committee, I am Sherwin Gardner, a consultant to the Grocery Manufacturers of America, Inc. GMA is an 85 year old national trade association of 140 members who manufacture approximately 85% of the foods sold in retail stores throughout the United States.

I retired last year as GMA Senior Vice President for Science and Technology after 14 years at the Association. Prior to that, I served at the FDA for nine years, seven of them as Deputy Commissioner. I was also a member of Secretary Sullivan committee in 1990 (the Edwards Committee"-Advisory Committee on the Food and Drug Administration) to study the FDA and make recommendations for improving its performance and effectiveness.

I appreciate the opportunity to appear before the committee to present GMA's views on the federal food safety system.

My statement addresses the four issues specifically requested by the committee. Before discussing these issues, I should like the committee to note that the GMA supports a strong and effective FDA. The agency's responsiveness to issues and its credibility with the American public and the food industry are key components in assuring a safe food supply. Of equal importance is excellence in the agency's scientific capabilities and resources.

To maintain this excellence, it is very important that Congress fully fund the Agency from general revenue. FDA's food, drug, biologics and medical device responsibilities directly touch the lives of every American each day. The safety of our food and medicine should be a very top priority and federal responsibility. Over the years, GMA has appeared before the Appropriations Committees and has supported full funding of the Agency.

At the same time, however, all of us need to do a better job managing what resources we have to do our jobs. The food industry has embarked on a massive efficiency and productivity program. Layers of management are being removed. The emphasis is serving the American consumer by cutting costs, reducing inefficiencies and increasing

productivity. We respectfully request all federal agencies, including the FDA, should consider similar actions.

The approvals of food additives, controls of imported foods and the timely completion of regulatory proposals, are examples of areas in which the FDA must improve. The opportunity to improve agency performance and efficiency is why we are encouraged by the interest in "Reinventing the Federal Food Safety System."

The Committee should note, however, that a food safety system encompasses more than just the application of inspection resources. Indeed, like HACCP, food safety in its broadest sense requires a total systems analysis. The agency or agencies charged with the responsibility for assuring food safety must be prepared to carefully address the practicality of its policies in achieving public health protection, and must have the scientific and technical resources as well as an understanding of the industry sector it is regulating. Further, consideration must also be given to the differences in laws that apply to the different sectors of the food industry.

1. FDA's capability to ensure the safety of the nation's food supply.

FDA already has a strong and effective array of enforcement tools, ranging from plant inspection, to court-ordered product seizures, injunctions and criminal penalties. The agency also has developed, with the cooperation of the regulated industry, effective regulations for assurance of safety of acidified foods and for thermally processed low acid foods. In our view, these are sufficient to ensure the safety of the nation's food supply if they are applied in the most cost-effective manner.

The agency has proposed its mandatory HACCP regulations for seafood under its current authority. These proposed regulations would extend the use of a widely applied, industry developed voluntary approach for assuring the production of safe food. GMA supports the voluntary application of HACCP in the seafood industry, with selected mandatory applications where scientifically justified. *GMA* also supports, in principle, the application of HACCP to the seafood industry, although FDA's proposal overreaches in records access and also lacks the essential flexibility needed in any HACCP program. These and other flaws, if not corrected, seriously jeopardize effective HACCP implementation and will result in a waste of FDA and industry resources with no offsetting gain in public health protection.

A critical factor in FDA's application of HAACP, besides establishing appropriate and flexible administrative provisions, is having an adequately trained inspection force to ensure compliance with these regulations when they are finalized. GMA has been cooperating with the agency in developing training programs for FDA inspectors in order to help ensure that the agency's inspectors are technically qualified in understanding HACCP techniques.

We believe that both human and dollar resources will continue to be an area of difficulty for the FDA. This makes it all the more important that its inspection programs, including

HACCP, are carefully focused on the most critical aspects of safety assurance systems. FDA's success in implementing HACCP will depend to a large extent on this factor. An overly detailed, prescriptive approach to HACCP will be counterproductive, and fail to achieve any gains in inspection efficiencies and effectiveness. The result will be less rather than more safety assurance.

I note in passing that the FSIS is also considering the implementation of HACCP procedures in its meat and poultry inspection operations. Similar considerations of focused applications and training apply equally to the FSIS situation.

In addition to its inspection and enforcement responsibilities, FDA is exploring ways to improve the effectiveness of its pre-marketing review responsibilities. This is an area in urgent need of improvement. FDA has made some management changes and published proposals to update its toxicology standards for evaluating food additives. These are well intentioned efforts that GMA supports. However, the proposal is scientifically inappropriate in several areas and would add unnecessary burdens both to food additive petitioners and to agency scientific staff. GMA also believes that the agency could materially improve its effectiveness in safety reviews by adopting the use of expert scientific advisory committees for evaluating food additive petitions, as it has for new drugs. Failure to address these issues quickly is an enormous disincentive to investments in new food technology, and is to the ultimate detriment of consumers.

2. Prevention, control, reduction or elimination of the primary risks of food illness. Food safety is the food manufacturer's fundamental responsibility. FDA's inspection activities are inherently well suited to this purpose by focusing on manufacturer activities in implementing systems of quality assurance and control. . FDA plays a key role in helping to define GMPs and other food safety standards, but the impressive record of food safety in the U.S. primarily reflects the conscientious efforts of food manufacturers to ensure the quality and safety of their products. In fact, HACCP was developed by the food industry nearly 25 years ago, and has since been widely applied voluntarily by manufacturers. FDA's role should be to verify how well these HACCP programs are being carried out by food manufacturers, to establish realistic policies, to contribute to the scientific knowledge base about food risks, and to undertake enforcement actions in a timely manner when HACCP programs and their scientific support base are not in compliance with regulations.

The voluntary adoption of an effective food safety approach should be encouraged by the FDA. HACCP is designed to reduce or eliminate food borne illness by controlling the truly critical safety risks in food processes. This approach has already demonstrated its effectiveness and is being adopted world-wide by standards setting and regulatory bodies.

3. Major components and guiding principles of an optimal federal food safety system. One of the strongest recommendations of the Edwards Committee in its May, 1991 report to HHS Secretary Sullivan was that "The FDA must clearly define its overall mission and develop a formal Statement of Purpose." As part of the report, the

Committee provided an example; it is appended to this statement. Last July, Commissioner Kessler issued a mission statement that had been developed by the agency; it incorporates many of the features of the Committee's example; it, too, is appended to this statement. GMA is in agreement with the Commissioner's mission statement and the principles incorporated within it. It is built upon a sound scientific and legal base, clearly understandable regulations, and involvement of the public, industry and other parties.

This agency statement of purpose is certainly applicable to the question raised about the guiding principles of an optimal food safety system. With respect to the options for developing and implementing such a system, that is the subject of the forth issue raised by the Committee's invitation to this hearing.

4. Consolidation of all food safety responsibilities under the FDA.
GMA believes that, for the time being, the two agencies - FDA and FSIS - should continue to be separate, for several reasons.

First, the technologies and constituencies of the regulated sectors are dramatically different, and would likely involve an extensive accommodation period, which would be highly disruptive to improvements being undertaken separately by both the FSIS and the FDA. By technologies I am referring not just to the differences in preparing fresh meats and poultry and in processing packaged foods. The entire production, distribution and marketing systems of these two types of food products are different, and require appropriate knowledge and capabilities to control effectively.

Second, the very broad scope of FSIS responsibilities would overwhelm FDA's management systems, and detract from its other important work in the areas of drugs, biologics and medical devices. The study undertaken by the Edwards committee showed that food programs clearly took second priority to medical products programs in resource allocation and policy direction. As an example, in the foods area, FDA needs to fully implement an effective data management and communication system for controlling imported foods. An agency that lacks such basic management tools is not in a position to expand its direction of additional food inspection activities, particularly when the industry subject to those activities is so dissimilar to those now inspected by FDA.

Third, submerging a combined operation of the size of FDA and FSIS within the Department of HHS is not likely to improve its performance because of the multiple management layers that would exist. The Edwards Committee which looked at FDA's activities three years ago concluded that, because of multiple layers of supervision in HHS, FDA should be given independent status within the Department to enhance its effectiveness. The Committee's concern about delays in communications and multiple levels of clearance for actions would argue against enlarging FDA within HHS by adding the FSIS. Indeed, the food function within FDA would become larger than the entire agency is today, which suggests that there be two agencies-- a Drug and Medical Products Administration and a Food Safety Administration. In our view, consolidation of food safety functions within HHS is not practicable.

The Committee should also note that some food safety responsibilities reside with the EPA for establishing pesticide residue safety requirements. If "all food safety responsibilities" are to be considered, then this aspect, too, should be taken into account. Clearly, pesticide residue safety has been in the forefront of public concern for a number of years. FDA exercises a key role in doing the inspection and enforcement part of this food safety function. Why should not the standards setting responsibilities also be vested in FDA for greater efficiency? FDA clearly has the scientific risk assessment qualifications to do this. In fact, FDA was responsible for the entire function before the establishment of EPA in 1970.

In a similar manner, the USDA has responsibilities for the inspection and enforcement of animal drug residues. FDA has the responsibility for approval of the drug products and establishing the safe residue levels. Again, if "all food safety responsibilities" are to be consolidated, this, too, should be considered.

In conclusion, food safety is recognized as important and is being actively managed by FDA and USDA. A number of key initiatives and reorganizations have begun and those efforts should be completed. With respect to FDA, GMA is eager to work with the appropriate Committees of the Congress and the FDA to design an approach that would more carefully target general revenues to top food safety priorities: particularly pesticide monitoring, food plant inspections and import inspections at the border. In other areas important to the food industry and consumers, such as approvals of new foods and ingredients, GMA urges the FDA to develop more efficient processes to help improve the speed of such reviews.

That completes my prepared statement, and I would be pleased to respond to any questions the Committee may have on this subject.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 15, 1993

MEMORANDUM

TO: All FDA Employees

FROM: Commissioner of Food and Drugs

SUBJECT: FDA's Mission Statement

I am pleased to send you FDA's mission statement, which includes our vision for the future. This statement is not just more words on more paper. It embodies this agency's proud tradition and provides a blueprint for the future.

The statement represents the work of a cross-section of employees as part of FDA's strategic planning process. During this process we asked some basic questions: What is FDA? Who do we serve? What is our contribution? Where do we want to be as an agency twenty years from now?

In articulating FDA's mission we have affirmed our central role in protecting the public's health. Fulfilling that responsibility requires us to set priorities, draw on the best science and scientific expertise available, and work together as a team to develop and implement policies that protect and promote the health of all Americans. Our success will also depend on working closely with members of both the public and private sector, and with other nations.

I want to thank all of you who helped develop this statement. And I want to thank all FDA employees for the hard work and commitment that will help us to realize our goals.

David A. Kessler, M.D.

Attachments

FOOD AND DRUG ADMINISTRATION

Mission

THE FOOD AND DRUG ADMINISTRATION (FDA) IS A TEAM OF DEDICATED PROFESSIONALS WORKING TO PROTECT AND PROMOTE THE HEALTH OF THE AMERICAN PEOPLE.

FDA is responsible for ensuring that:

- Foods are safe, wholesome, and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.
- Regulated products are honestly, accurately, and informatively represented.
- These products are in compliance with the law and FDA regulations; noncompliance is identified and corrected; and any unsafe or unlawful products are removed from the marketplace.

Principles

We strive to:

- Enforce FDA laws and regulations, using all appropriate legal means.
- Base regulatory decisions on a strong scientific and analytical base and the law; and understand, conduct, and apply excellent science and research.
- Be a positive force in making safe and effective products available to the consumer, and focus special attention on rare and life-threatening diseases.
- Provide clear standards of compliance to regulated industry, and advise industry on how to meet those standards.
- Identify and effectively address critical public health problems arising from use of FDA-regulated products.
- Increase FDA's effectiveness through collaboration and cooperation with state and local governments; domestic, foreign, and international agencies; industry; and academia.
- Assist the media, consumer groups, and health professionals in providing accurate, current information about regulated products to the public.
- Work consistently toward effective and efficient application of resources to our responsibilities.
- Provide superior public service by developing, maintaining, and supporting a high-quality, diverse workforce.
- Be honest, fair, and accountable in all of our actions and decisions.

FDA VISION

FDA in the year 2000 will be...

- **A strong science-based Agency** – to accurately detect and assess health risks, and to set appropriate standards.
- **A trusted Agency** – to enforce the Food, Drug, and Cosmetic Act fairly, uphold safety standards, and protect consumers.
- **An enabling Agency** – to steward needed products and to promote public health.
- **A collaborative Agency** – to strengthen ties to scientific, health provider, and regulatory communities both domestically and internationally.
- **A high-performance Agency** – to capitalize on state-of-the-art information and communication technologies and management systems to enhance performance.
- **An employee-valuing Agency** – to recruit, develop, and advance employees equitably, and to position the Agency to meet the changing work force needs of the 21st century.

The FDA principally serves the general public in its health and safety mission. The FDA also recognizes its responsibilities to the industries that it regulates and will work with them in shepherding new technologies to the marketplace. Thus it strives to maximize public health protection while minimizing regulatory burden.

"SAMPLE STATEMENT OF PURPOSE"

The mission of the Food and Drug Administration, acting pursuant to statutory authorization, is to protect and enhance the health of the American public.

The Agency achieves this mission by:

- ensuring that the food supply is wholesome and safe; that drugs, biologics and medical devices are safe and effective; that cosmetics are safe; that radiological products are safe and do not expose the public to unnecessary radiation; and that all of these products are honestly and informatively labeled;
- enforcing the laws from which the Agency derives its responsibilities in a timely, fair and decisive manner;
- facilitating the timely availability of the products whose use the Agency must authorize.

The procedures the Agency uses to achieve this mission must be in accordance with the law, consistently followed, fairly administered, and promptly concluded.

These are the principles that should guide the FDA's actions:

- To endeavor to employ a sufficient number of qualified persons motivated to accomplish its mission. To ensure that these individuals receive the compensation, training and other resources necessary to maintain a high level of expertise, morale and productivity.
- To fairly and firmly exercise its authority, safeguarding the well-being of those who receive and use the products it regulates and respecting the legal rights of those who manufacture, market and consume those products.
- To carefully reason and thoroughly explain its decisions, and base its actions upon sound scientific and legal analysis. To take into account all legally relevant and sound data, no matter where derived, and balance the appropriate benefits and risks when making these regulatory decisions.
- To encourage compliance with legal requirements by providing clear guidance on how such compliance can be achieved. Policies and procedures should be publicly available and clearly set forth in writing, and widely disseminated.
- To invite active participation by the public to establish its priorities and expectations.
- To encourage participation, cooperation, and alignment with consumers, industry, academics, and state and local governments with its mission for the purpose of fostering a uniform national system of health regulation. To achieve regulatory uniformity, by appropriate means, when there is need for a consistent national policy.
- To be active participants in the formulation of the Administration's health policy and in the development and implementation of legislative programs.
- To promote cooperation and comity with respect to international health product regulation. To seek to develop consistent health regulatory policies with other governmental authorities, both within and outside the United States.
- To be involved in and encourage the education of the public and professionals concerning its regulatory processes and public health issues related to the products it regulates.
- To conduct research necessary to accomplish its mission, without duplicating the activities of industry, academia, or other government agencies.
- To conduct its activities in a manner that focuses on the overall improvement of the public health.

Mr. TOWNS. Mr. Weddig.

STATEMENT OF LEE J. WEDDIG, EXECUTIVE VICE PRESIDENT, NATIONAL FISHERIES INSTITUTE

Mr. WEDDIG. Thank you, Mr. Chairman.

My name is Lee Weddig, I am executive vice president of the National Fisheries Institute. We work for the fish and seafood mongers of the country and the people who catch and process seafood. It seems that this hearing has almost turned into a seafood hearing rather than one looking at the overall structure of our food safety apparatus.

We have been working on this for a long time. In fact the first time that I testified here on seafood safety was in 1967. There has been active interest in Congress in improving the seafood inspection system for about 27 years. Because Congress couldn't make up its mind through the years as to exactly what it wanted to do, this is the reason that we went to the Food and Drug Administration last year and wrote to Secretary Shalala and said, "Why don't you get this thing off the dime and let's move forward with the HACCP approach." This is something that had been agreed upon as a way seafood safety could be better improved and perhaps useful in other parts of the industry as well.

Since then we have been very gratified by the reaction of the Food and Drug Administration, first because it created an office of seafood, which provided a focal point for policies and programs relating to the safety and the quality of our products and the regulation of our industry.

Second, from that office came the HACCP proposal, which is a sweeping new regulatory scheme that is going to put some very significant new responsibilities on every company in the seafood business. We are working to make it very effective.

Since it was announced at the end of January, our organization has had more than 20 different committee meetings and workshops to make sure that the 1,000 member companies are aware of what is happening and to get their input. The last of these meetings was yesterday, Mr. Chairman, and it consisted of five companies from Brooklyn who came down to discuss the HACCP proposal as to how it would relate to the smoked fish business, which is concentrated in Brooklyn. These people are in the midst of preparing HACCP plans for the salmon smoking industry that is centered up there, and for the hot smoke fish business which is centered in Brooklyn.

They only have one question. They have never had an incident of illness coming from their plants and yet they are taking on a great new responsibility here. They are willing to do it and are well on their way toward getting it implemented, but with all the talk about safety I think we should look at the actual record. We will see that incidents from seafood illness, seafood-caused illness, are no worse than any of the other animal foods and much better than some.

In fact, if you look at the statistics, it looks like about one-tenth of 1 percent of that 81 million potential cases are caused by seafood. That is a very good record and we are trying to make it better. So in looking at the HACCP program, which we endorse and how it could be made better, we have several points.

The first is we think that FDA must be able to review and update its guidance on a very systematic basis to accommodate new technology as it comes along.

Second, this program cannot become a paperwork monster causing the generation of records for their own sake. We fully endorse the comments made by my colleagues here about the need to keep the recordkeeping and record access confined to the critical control points relating to safety.

The third point, and this is a big one, is that the HACCP system must work internationally. We have heard talk here this morning about the difficulty of inspecting imports. You cannot inspect all the imports. There are too many of them. The only way it can be done, then, is to get the other competent nations around the world to adopt preventive control systems and have an exchange of responsibilities so that our products can move freely into the other markets and the products from competent countries can move freely into the United States. That has to happen for seafood and the other products as well if it is going to function at all.

The fourth point is that FDA must develop a very strong, well-defined working relationship with the State governments and the other Federal agencies if this HACCP program is going to work. There is need to make sure the resources of the National Marine Fisheries Service is integrated into the HACCP system. NMFS has 100 specialized seafood inspectors on staff and it has been involved in the voluntary program for more than 25 years. Tremendous expertise there. It has to be brought into the HACCP system in order to reduce the cost and the burdens on the industry.

The sixth point. There is need for legislative change to make the best use of the talent and resources of the National Marine Fisheries Service and the other agencies that have specific capabilities, such as the Department of Defense. We understand at this time that the FDA by law cannot deputize or assign its responsibilities to other Federal agencies. It can to the States but it cannot do it to the other Federal agencies. This does not make sense. That law has to be changed to take advantage of the manpower that is available.

Then, the new program has to be integrated with fishery management activities so that we can cutoff potential problems at the source. In other words, do not harvest fish that cannot be sold safely.

And the last point: we need to have a major effort to extend education and training to consumers and to the retail level. The statistics will show that most of the illnesses are caused by mishandling after processing. The only way we can cure that is by making sure consumers, restaurateurs, retail operators are well-educated and trained in the proper handling and in storage techniques.

So, Mr. Chairman, we think that we are at the beginning of a very important new era in food safety regulation in this country. It leads to the basic point of the hearing, and that is: "Should there be one agency?"

At this point in time we agree totally that the organization is less important than the philosophy: How should food safety be handled? Whether it is one box, two boxes, does not make a lot of difference. We would really hate to see the initiative and the enthu-

siasm that has been started here for something new and progressive such as the HACCP program get dissipated by quarreling over what agency should have it or by going through the political downside of trying to consolidate agencies, which is a very difficult thing.

That concludes my comments, Mr. Chairman, and I am open to any questions.

Mr. TOWNS. Let me thank you too for your testimony.

[The prepared statement of Mr. Weddig follows:]

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TESTIMONY OF LEE J. WEDDIG

EXECUTIVE VICE PRESIDENT

NATIONAL FISHERIES INSTITUTE

TO THE

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

OF THE

HOUSE COMMITTEE ON GOVERNMENT OPERATIONS

MAY 25, 1994

Thank you for the opportunity to provide testimony on the subject of "Reinventing the Federal Food Safety System." The National Fisheries Institute is a broad-based trade association of about 1,000 member companies involved in all facets of the commercial fish and seafood industry. Our members are located throughout the United States and include companies which harvest, process, market, import, and export fish and seafood products.

Enhancing food safety has been a dominant part of our work for many years. The Institute has been on record for the past eight years as supporting an improved regulatory program for the seafood industry. We are gratified that after many years of discussion and study, definitive progress is being made with the publication by the Food and Drug Administration of proposed regulations which would require the establishment of a preventive control system (HACCP) throughout the seafood industry.

Our support of an improved regulatory program for the industry is not based on concern that seafood products on the marketplace are inordinately unsafe, or that there is a public health crisis caused by seafood products. On the contrary, any objective review of actual illnesses attributable to seafood shows a very low rate of incidence, certainly no greater than for other animal protein foods. Furthermore, the unfortunate incidents that do take place are concentrated in a few well defined areas.

We have other important reasons for supporting a preventive control regulatory program. Included, of course, is the desire to correct the deficiencies which do produce the relatively few cases of illness that do occur. In addition, we recognize continuing changes in our industry that demand a more sophisticated regulatory approach to seafood safety and wholesomeness objectives. Our industry is characterized by its dependence on international trade, a wide variety of products and product forms, seasonality of production, a dominance of small businesses, and finally, a direct interaction with the natural environment which often contains conditions that are difficult to foresee and control. We believe that the recently proposed regulation calling for seafood handlers to establish and operate under Hazard Analysis and Critical Control Point systems is the most logical and effective way of enhancing the safety of seafood products.

The FDA proposal is impressive. It proposes succinct and generally very understandable regulations. It also includes a comprehensive hazard control guidance document which will be invaluable to the industry in meeting its obligations under the new regulations. The National Fisheries Institute is preparing its comments on both the proposed regulations and the guidance documents.

The move to a mandatory HACCP system is a very major step for our industry. It places a new level of responsibility on all

companies with significant burdens in monitoring and documenting their operations. Companies must not only produce unadulterated food, but also be able to prove that they have taken the necessary steps, on a continuous basis, to control critical hazards. The industry has worked on this process for more than five years. It was heavily involved in a cooperative program with federal agencies and state Sea Grant University food scientists to develop model HACCP systems for most processes in the industry. Many thousands of hours were devoted to the design and pilot testing of these systems. All of this work will serve us well as we move into the mandatory program. Many companies are already operating under HACCP principles.

The Food and Drug Administration has daunting responsibilities in its regulation of the American food supply. In addition to food safety concerns, these responsibilities extend to product wholesomeness, quality, labeling, nutrition and other areas. It also is responsible for overseeing the production and distribution of drug and medical devices. Congress has chosen to increase the agency's responsibilities but has not provided the necessary additional funding to fulfill all of the requirements. As a result, there are delays which can be extremely costly and frustrating to businesses, in turn leading to higher costs for consumers.

We are particularly concerned with delays at the port-of-entry for imported products. As mentioned, the seafood industry is characterized by its international scope. We import about 50

percent of our supply, and we export about 30 to 40 percent of our production. Moving merchandise through the ports-of-entry must be done quickly and efficiently. Unfortunately, when the FDA chooses to examine a shipment, delays of 30 or more days are routine. When a small company has hundreds of thousands of dollars tied up in merchandise waiting for FDA port-of-entry clearance, each day of delay is an expensive proposition. We are pleased that the agency is now taking some aggressive steps to help alleviate these problems. The new HACCP based program which shifts responsibility to the importer and overseas producers to provide documentation that the product has been produced under a preventive control system is the most far reaching and important change. We anticipate that products coming from those countries in full compliance with the new regulations will be able to move more swiftly through the ports-of-entry with benefits to the overseas producer, the importer and the consumer.

During the time the HACCP system is being established we are appreciative of the agency's attempts to bring innovative ideas to the port clearance requirement by allowing importers to utilize private laboratory facilities to provide documentation that product meets U.S. standards. Pilot programs are in place in several ports. We hope that they will prove to be successful and reliable so that they can be used throughout the country.

The lack of resources shows up in other areas as well.

We are particularly concerned with the amount of time it takes to review and approve petitions for changes in such basic areas as standards of identity and approvals of products as being Generally Recognized As Safe (GRAS). As an example, our organization filed a petition in 1986 to affirm the GRAS status of menhaden fish oil. Menhaden oil products have been sold for decades in Europe where they are used in margarine and cooking oil. There is absolutely no indication of human health problems. Nonetheless, our refined oil petition remains unapproved at the agency eight years after filing. GRAS status for partially hydrogenated oil has been approved, but the corollary modification of a margarine standard of identity remains tied up for months, although preliminary approval has been announced. It isn't right that time tables for relatively simple petitions be measured in years rather than months or weeks.

In response to the committee's second question, the Food And Drug Administration does set highest priorities on programs aimed at minimizing or eliminating primary risks of food borne illness. In the realm of seafood products, this is a complicated business because of the unique characteristics of the industry and its products. Specifically, the effect of environmental conditions is the most critical area that could affect the safety of seafood products. Statistics show that two of the three leading causes of illness from seafood products are directly related to environmental conditions and are not affected by handling procedures. These are the incidents of ciguatera, the result of

algae growth in certain tropical reefs and the incidents caused by the consumption of raw molluscan shellfish from contaminated waters. In the latter case, cooking resolves the problems. However, the appeal of molluscan shellfish to many is raw consumption. Conversely, ciguatoxin, is not destroyed by cooking. The only control mechanism is to avoid fishing in areas that may harbor the algae growth. The incidents of Ciguatoxin poisoning are confined primarily to tropical areas, and very often are caused by recreationally caught fish.

The third major cause of seafood illnesses is high levels of histamine found in some species of fish which have been improperly refrigerated. This problem can be controlled through good manufacturing practice and attention to temperature controls. The new HACCP program will address both the environmentally caused problems as well as those caused by poor handling.

FDA has been making constant improvement in its operating programs regarding seafood safety ever since the establishment of an Office of Seafood at the Agency three years ago. For many years we had been concerned about a lack of specific policy and program attention for seafood products at the FDA. The development of the HACCP regulations and the guidance document is a direct result of the new Seafood office. In addition, the Office has developed a stronger working relationship with the Interstate Shellfish Sanitation Conference, an organization made

up of state governments who have primary responsibilities for monitoring the molluscan shellfish growing waters.

As to how the existing FDA safety program is designed to minimize primary risks, we have seen the agency devote its attention to potential high risk areas very effectively. As an example, when several South American countries experienced cholera epidemics, the agency immediately shifted its import inspection emphasis to product coming from those countries. As a result, we were able to maintain trade, but without any incidence of the disease from commercial product.

When concern was raised about the possibility of listeria monocytogenes being found on cooked ready-to-eat products, the agency developed guidance and worked with the states and the National Marine Fisheries Service in producing information on how this potential hazard could be better controlled. Although there have been no incidents attributable to this bacteria in U.S. commercial seafood products, the action of the agency has produced a much better understanding of potential risk within the industry and has zeroed in on preventive actions which so far have proven to be quite successful.

Since seafood imports are a major part of the supply and it is impossible for the agency to conduct physical inspections on all seafood imports, it is essential that the available resources be concentrated in areas that have the greatest risk. As mentioned, the attention paid to product from areas where cholera is endemic has been successful. Over the years, import

inspections were concentrated on products from countries where salmonella was prevalent and on species that had the potential for higher than desired levels of natural mercury. The agency is able to shift its attention to the highest risk areas. We have seen greater proficiency with computerization of import activity.

In the future, we believe that the immediate need is to make the proposed HACCP system work. This will be a mammoth task for both the Food and Drug Administration and the industry. There are several key points which must be kept in mind as the system evolves.

The first is that the guidance provided to the industry and to the inspection force itself must be reviewed and updated in a systematic fashion. The ability to recognize and control potential hazards will be changing with new technology and with the recognition of new hazards. It will be critical that the agency be able to devote necessary manpower and resources to keeping the guidance document as current and innovative as possible in order to increase its effectiveness and to reduce costs of operations whenever possible.

Secondly, it is critical that the program not become a paperwork monster, loaded down with more records than can be scrutinized and analyzed. This is a reason why we believe that basic sanitation requirements should not be included as HACCP records unless the requirement is specifically tied to a critical

Control Point. Record keeping cannot be an end or objective for its own sake.

The HACCP system must work internationally. Fortunately, the trend towards preventive control systems such as HACCP is well on its way in other countries. The European Union, Canada, other nations are adopting this approach to food safety control. As the Japanese government also moves toward this type of monitoring requirements, all of the major markets for seafood in the world will be on the same level. This in turn will force the seafood exporting nations to move rapidly to acceptable domestic HACCP regulatory requirements. In order to maintain supplies to the consumers of the United States and to fulfill our free trade obligations and to protect the ability of our exports to move in the international market place, it is incumbent upon the FDA to devote immediate and considerable effort in negotiating international agreements with our key seafood trading partners. The ability for the industry to function will be dependent upon major nations having similar systems in place. This will not only produce safer products, but also relieve pressure at the port-of-entry. It will allow resources to be devoted to those problem areas not covered under a foreign government's HACCP regime.

Cooperation with state and federal agencies is also needed. The FDA must develop a very strong, well defined working relationship with the state governments and with other federal agencies who have responsibilities within the seafood arena.

Much of the on site inspection work under the HACCP program can be accomplished by state agencies, especially in those states where seafood production is a major industry. The FDA needs to make certain that state agency personnel, as well as its own personnel are properly trained in the new HACCP technologies in order to provide uniform enforcement throughout the country. Training will be critical. It must extend down to the state level. There is no point in duplication in which both federal and state agents are trekking through plants to examine the same records and make their own judgments as to the effectiveness of individual programs.

The resources of the National Marine Fisheries Service (NMFS) must be integrated into an effective HACCP program. This agency has several hundred specialized seafood inspectors on its staff and has been involved in the voluntary seafood inspection program for more than 25 years. It has tremendous expertise as well as resources that are being paid for by the seafood industry users.

As the HACCP requirements move forward, it is only logical that those companies that utilize the fee-based National Marine Fisheries Service inspection program be considered in compliance with the FDA regulations. FDA's allocation of its own inspection resources should recognize that that those hundreds of establishments in which the voluntary program is being implemented need not receive attention from the FDA inspectors.

Their time would be better spent dealing with the companies that have not employed the NMFS program.

There is need for legislative change to make best use of the talent and resources of the NMFS as well as with other agencies such as the Department of Defense. At this time, the law does not permit the FDA to deputize or assign its responsibilities to other federal agencies, even though it is able to do that with state governments. This makes no sense. If the FDA is able to enter into memoranda of understanding in which the state agents are given responsibility to enforce FDA laws, there is no reason why similar agreements cannot be reached with other federal agencies who have well trained specialized personnel on their staffs.

The new program should also be integrated with fishery management activities that are the responsibilities of the U.S. Department of Commerce. Many of the potential problems with seafood safety are environmentally generated. The most effective prevention technique is to avoid fishing in areas where serious environmental hazards occur or to manage fishery harvest with safety as well as resource utilization objectives. The work of preserving habitat which needs urgent attention should be integrated with seafood safety needs.

Another major need is to extend education and training to consumers and to the retail level. Any study of illnesses reveals lapses and poor practice in restaurants, retail stores and in consumers' homes. There is no way that product will

remain safe when it is mishandled by the consumer or the retailer. Training and education of consumers at the elementary and high school level should include practical hygienic and handling instruction. This task has been made more urgent by the emergence of many more and larger ethnic populations whose dietary practices are different than what have been traditional here in the United States. Some of these practices are hazardous. As an example, several illnesses occurred two years ago on the West Coast from ingestion of fish that contained a algae induced toxin in the fish intestinal tracts. Eating fish whole is not common in the United States. However, in some ethnic groups, it is a common practice. The result was illness. The only solution is education to tell people they should clean fish before they cook and eat them.

Education will be enhanced when there is more uniformity in the messages. Unfortunately at this point in time, we have too many people determining what they believe is risk from low level contaminants in foods. The Environmental Protection Agency has been heavily involved in making fisheries risk assessments which in turn are passed on to state governments for use in advice to consumers regarding their ingestion of sport caught fish. The assumptions for risk assessments by the EPA are different than those used by the FDA. This is illogical and extremely confusing.

The EPA should get out of the risk assessment business for food and leave that task to the FDA.

Finally, in respect to the recommendation by the National Performance Review to consolidate the Food Safety and Inspection Service with the food safety responsibilities under the Food and Drug Administration, at first reading the idea appears to have merit. However, the political ramifications of creating such an entity are considerable. As I just indicated, assessing risk factors related to food consumption is shared by other agencies than FSIS and FDA. Both the National Marine Fisheries Service and EPA are involved in food safety activities. The Defense Department has food safety responsibilities for troop feeding and I am certain other agencies also have responsibilities.

The FDA and the seafood industry are in the midst of a massive restructuring of the way seafood operations and product will be inspected in the future. This new state-of-the-art system, which is based upon the best scientific advice available, promises to bring substantial benefits to American consumers and the industry.

We would be dismayed if efforts to reorganize the bureaucracy of government distracted officials from the substantive challenges they face in designing and installing this new HACCP program.

Combining the two lead agencies by itself will not provide a streamlined consolidated operation. I believe the benefits of a more consistent food safety policy can be achieved just as well

by persistent coordination between the key agencies such as has been demonstrated in such matters as food labeling and development of HACCP concepts. We encourage this type of coordination at the top levels of the respective agencies rather than spending too much effort on trying to figure out whether a single agency would produce benefits for the public.

The question of how many or which agencies should have food safety responsibilities cannct be answered until agreement on food safety program philosophy, principles and methodology are determined. Reorganization doesn't answer those questions. Seafood consumers and the industry expect to be well served by the new FDA program. We would not want it to be disrupted.

Thank you again for the opportunity to provide comments on this subject. I would be happy to answer any questions now or later for the record.

Mr. TOWNS. And let me begin by first saying that I support HACCP, but my concern is that I do not think FDA has the resources to make it work. That is my concern. But it does not mean I do not support approach. I support it fully.

Let me raise a few questions here: Is FDA's proposed regulation for HACCP sound?

Ms. DUGGAN. We believe the essential features of it are sound. I think the food industry has some concerns about the scope of some of the features, but the essentials of the approach are based on sound science and HACCP principles that have been espoused by the industry for some time. NFPA has been involved in teaching HACCP programs in plants and educating our members about it, and I think we would all agree that the essential approach is sound.

We are going to be asking in our comments that are due next Tuesday for FDA to make some revisions in certain places and we have mentioned those to you: Records access, and focusing on things that are not essentially food safety but beyond food safety. We will all be asking for revisions, but I think we generally support the approach.

Mr. WEDDIG. May I comment, Mr. Chairman.

Mr. TOWNS. Sure.

Mr. WEDDIG. I think the soundness of the HACCP approach is evident in the record that has been achieved by the low acid canned food business; 25 percent of seafood products are canned. Ever since HACCP was put into place, the modified HACCP approach, concentrating on the true risk areas of critical control points was imposed throughout the canned seafood industry and the rest of the low acid canned food business, the record has been exceptional. I can't recall of any incidents that have come forward since that time. So HACCP does work, and it is a sound approach.

Mr. TOWNS. Do you believe that FDA has the necessary resources? Do you believe that FDA has enough resources to implement it and maintain it at a quality level?

Mr. WEDDIG. I think if the FDA is able to make use of the resources that exist in this country, it will have adequate resources.

Mr. TOWNS. Exist in this country?

Mr. WEDDIG. Yes, sir.

Mr. TOWNS. Oh.

Mr. WEDDIG. They basically have to integrate the capabilities of the State governments and the other Federal agencies that have inspection capabilities. This will enhance the effectiveness of the program tremendously. Every State that produces seafood has its core of inspectors.

What we are concerned about is duplication. The seafood plants in Alaska will be overrun by the Alaskan inspectors as well as by the Federal inspectors. We have had incidents in the past where three or four separate agencies would come in and inspect the same plant. Coordination has to be improved. With the HACCP program, let us find out which agency is most capable and available and delegate responsibility to one of them. Spread these resources out so that there can be a more effective job.

Ms. DUGGAN. May I comment on that?

Mr. TOWNS. Sure.

Ms. DUGGAN. Our viewpoint is that FDA, without HACCP, is not going to have adequate resources because the current inspection system is based on visual inspections that cannot address the real priority food safety questions. Over time there will be tremendous efficiencies in the FDA resources with the HACCP system. There may be a spike in implementing it in the beginning, but over time it will be a tremendous efficiency.

Mr. TOWNS. Mr. Weddig, why not label raw oysters?

Mr. WEDDIG. Well, we basically think that medical advice should come from medical people, as a starter. The particular situation is a difficult one and we do not question that at all. We might point out that the incidence of vibrio vulnificus is in the warm waters of the Gulf of Mexico. It can also be contracted by people at risk just by going into the surf.

The risk from this particular natural marine bacteria is not confined to consumption of raw oysters. Let us put warning labels on the beaches, too, and say, if you are at risk, do not walk in the water.

Mr. TOWNS. I would not fight that. I would support that, especially if it is dangerous.

Mr. WEDDIG. But the incidents really are extremely low overall. We would not have objection to the concept of consumer advice that is specific and to the point and is very accurate to be required on those particular products where this risk exists. We do object to a blanket approach that would target all molluscan shellfish or molluscan shellfish products that have never been implicated with this particular problem.

Shucked oysters have not been implicated. The containers that you see in the marketplace have not been implicated in this. We are talking about a very localized and seasonal situation, so the advice should be targeted to where it will do the most good.

Mr. TOWNS. I see my time has expired and I would like to now yield to a very active and effective member of this committee.

Mr. SCHIFF. Thank you, Mr. Chairman.

Mr. TOWNS. Mr. Schiff.

Mr. SCHIFF. Flattered.

Ms. Duggan, you made a special emphasis on the point that under existing law the Food and Drug Administration has the ultimate weapon, so to speak. People can be criminally prosecuted and put in jail for violating the FDA laws.

Ms. DUGGAN. Without knowledge or intent.

Mr. SCHIFF. In the last 5 years, how many people have gone to jail for violating the Food and Drug Act?

Ms. DUGGAN. I am not sure I can answer that question for you off the top of my head, but we will be happy to provide it for the record.

Mr. SCHIFF. I would——

Ms. DUGGAN. There have been people who have gone to jail in the past. I cannot tell you in the last 5 years, but we would be happy to provide that for the record.

Mr. SCHIFF. I would kind of like to know.

Ms. DUGGAN. There are significant enforcement activities, and criminal liability is the ultimate enforcement weapon, but FDA has many, many others short of that that they can use, and——

Mr. SCHIFF. Your industry would not want them to place an emphasis on criminal prosecution as their primary means of regulatory authority.

Mr. TOWNS. If the gentleman would yield. There were only two.

Mr. SCHIFF. In the last 5 years?

Mr. TOWNS. In the last year.

Ms. DUGGAN. It would depend on the severity of the violation, of course. We believe in active enforcement of law.

Mr. SCHIFF. I just thought with respect to your emphasis on that potential authority, based upon my understanding of the few number of cases that are ever brought, it was a bit disingenuous in terms of something active today, or I think that the industry would want to be active today as a means of enforcement when we are talking about regulatory approaches.

Ms. DUGGAN. We consider it to be a strong deterrent, a very strong deterrent.

Mr. SCHIFF. All right. Fair enough.

Mr. Weddig, we seem to be talking a lot about oysters here today. I am not sure I can look at an oyster again for a while.

Mr. WEDDIG. Well, please do. In fact, I wanted to know what the chairman was going to do with those oysters that he had.

Mr. SCHIFF. I will let you know if they appear in the Members' dining room.

Mr. TOWNS. My problem was, were they handled properly?

Mr. WEDDIG. Depends on how you took care of them.

Mr. SCHIFF. But, seriously, I did not fully understand the answer. I understood the generalities of the answer that labels should not be required where there has not been a demonstrated link between a particular product and a particular health hazard. I grasp that. I think that makes sense.

But as the representative of the industry, can you be specific as to where you believe there is such a demonstrated link that a warning would be appropriate?

Mr. WEDDIG. I think the area is fairly well confined to the Gulf of Mexico and south Atlantic waters during the summer months. The incidents that have occurred, the unfortunate ones, have been primarily from the oyster served on the half shell. We have not seen any correlation with the shucked product, for whatever reason. Mainly, I suspect, because most people do cook the shucked product. Also this particular bacteria, is a very, very weak bacteria in the sense of its ability to be damaged by a lot of circumstance.

It is very sensitive to heat, as a beginner, and it also seems to be knocked down by proper refrigeration, by freezing and even the shucking process, which involves very good handling in a shucking plant. That seems to have been very beneficial. So it seems to be particularly a problem in the raw oysters served through restaurants and on the half shell.

For this we would see there is a place for consumer advice to take place. We have published brochures through the years and given them to the medical profession to try to make sure they would give good advice to the people who are at risk.

Mr. SCHIFF. One final question. I want to go back to a statement Dr. Frank made testifying on behalf of the FDA that, who said that?

Mr. TOWNS. Dr. Shank.

Mr. SCHIFF. Dr. Shank, pardon me. Thank you.

Dr. Shank said the responsibility for safe food is with the industry. The FDA, or the government, for that matter, has the oversight, has the oversight responsibility. He also testified that he believes that 9,000 or more people a year die from contaminants in foods.

And I would like to know, does the industry, and I realize you are not the whole industry here, but certainly between the three of you, you are an effective part of the food industry, do you agree with that figure? Do you think the idea that 9,000 or more people die a year from food contamination is an accurate estimation?

Ms. DUGGAN. Those are the only figures the industry has because they are provided by the CDC and those are the stated figures that are used in the industry and with the government. Yes, those are the numbers.

Mr. SCHIFF. Well, I just want to say that if I were in an industry that at least the most accurate statistics that are available demonstrated that 9,000 people or more die a year from contamination of my product, that it would spur me to as much as I could do immediately, to try to reduce that number to the lowest possible point, and I certainly hope that the industry is reading it the same way I am.

Ms. DUGGAN. Mr. Schiff, just to comment on that, we agree wholeheartedly there is tremendous room for improvement which is why we are so supportive of moving into this new era of science-based prevention for food safety. And that is what HACCP will do for us. It is a technology that has real opportunity really to increase food safety, as opposed to some of the other things we do that might improve bureaucracy but will not have real food safety improvements in the marketplace: Helping people not be sick and not have fatal injuries.

Mr. SCHIFF. If I could have another minute.

I agree that we want to look for effective solutions and not cosmetic solutions. I have to be the first to acknowledge I have seen a certain area where the Congress, in my judgment, moves more toward cosmetic solutions to certain problems than effectively getting the job done. What I am trying to indicate is, to me, an atmosphere of what ought to be basically a crisis.

I mean, thousands of people are dying each year from contaminants, and, therefore, I agree with your looking for effective responses and not just feel good kinds of approaches, but words like: "We are looking toward," and "we are working for," I mean, I would sure light a fire under the process.

Ms. DUGGAN. One of the things I think is important to remember is that most of those instances of foodborne illness do occur at points out of the production process. The incidence of foodborne illness and death related to a processed product is very rare, extremely rare, and the National Food Processors Association and its scientists and its laboratories have been involved in trying to create the processes to make sure that that is improved.

But most of those instances are at points much closer to the consumer: in the home, in retail establishments, in restaurants, and that sort of thing, and it is a very diffuse problem. It is dif-

ficult to control. It does require linkage between FDA and the State and local government, and it is just something, to make sure you know the record, that it is much closer to the consumer than food production and food processing.

Mr. SCHIFF. I certainly acknowledge the three of you together as representatives of industries are a part of an overall system. If I had more people involved in the system in front of me, I would try to deliver the same message.

Thank you, Mr. Chairman.

Mr. TOWNS. Thank you, very much, and let me thank the witnesses.

At this time, I would like to ask unanimous consent to include a copy of the Congressional Research Service report on FDA's enforcement authority conducted at the subcommittee's request, without objection.

[The information can be found in appendix 5.]

Mr. TOWNS. Also, I would ask unanimous consent to hold the record open for 10 days to allow other interested parties to submit written statements for the record on FDA's food safety programs, without objection.

[The information can be found in appendix 4.]

Mr. TOWNS. What we have heard here today is nothing short of alarming and discouraging. FDA has failed to ask for the resources it needs to implement HACCP. If FDA needs more resources, it has an obligation and a responsibility to request these resources. FDA lacks the tools to ensure the safety of the Nation's food supply.

While FDA's proposed HACCP program for seafood is a step in the right direction, and I would be the first to say that, it will ultimately fail if it is not properly implemented. We cannot permit that to happen. Too many people are dying and suffering from tainted food and we need to correct that.

The hearing is concluded.

[Whereupon, at 12:20 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

REINVENTING THE FEDERAL FOOD SAFETY SYSTEM

(Fresh Versus Frozen Chickens and Other Issues Involving USDA's Regulation of Poultry Products)

THURSDAY, JUNE 16, 1994

HOUSE OF REPRESENTATIVES, HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE, AND INFORMATION, JUSTICE, TRANSPORTATION, AND AGRICULTURE SUBCOMMITTEE OF THE COMMITTEE ON GOVERNMENT OPERATIONS,

Washington, DC.

The subcommittees met, pursuant to notice, at 9:35 a.m., in room 2154, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the Human Resources and Intergovernmental Relations Subcommittee) presiding.

Members present from the Human Resources and Intergovernmental Relations Subcommittee: Representatives Edolphus Towns, Thomas M. Barrett, Donald M. Payne, Steven Schiff, John L. Mica, and Rob Portman.

Members present from the Information, Justice, Transportation, and Agriculture Subcommittee: Gary A. Condit, Stephen Horn, and Karen L. Thurman.

Also present: Representatives Collin C. Peterson and Frank D. Lucas.

Staff present from the Human Resources and Intergovernmental Relations Subcommittee: William M. Layden, professional staff member; Martine M. DiCroce, clerk; and Martha B. Morgan, minority professional staff, Committee on Government Operations.

Staff present from the Information, Justice, Transportation, and Agriculture Subcommittee: Edward L. Armstrong, professional staff member; Aurora Ogg, clerk; and Diane M. Major, minority professional staff, Committee on Government Operations.

Mr. TOWNS. The subcommittees will come to order.

At this time, I would like to yield to the gentleman from New Mexico, Congressman Schiff, for a very important introduction.

Mr. SCHIFF. Thank you for yielding, Mr. Chairman.

Mr. Chairman, I would like to welcome to the U.S. House of Representatives again, and in particular to the Government Operations Committee, Congressman Frank Lucas of the 6th District of Oklahoma.

Congressman Lucas is a cow/calf operator, and he asked me to say that fast hoping that no one would pick up that means beef

producer. However, he did assure me that it means absolute neutrality between him and the poultry producers here at the coming hearing.

Congressman Lucas, welcome, and we are glad to have you on the committee.

Mr. LUCAS. Thank you for the opportunity to be here, and I certainly plan to be diligent in my work with the chairman and the rest of the committee.

Mr. TOWNS. We are delighted to have you on the committee and to know that we have a beef producer here. We need a beef producer.

Thank you very, very much, Congressman Schiff.

At this time, I would like to make an opening statement.

The Government Operations' Subcommittee on Human Resources and Intergovernmental Relations and the Subcommittee on Information, Justice, Transportation, and Agriculture will examine the U.S. Department of Agriculture's policy on when a chicken is labeled fresh and when it is labeled frozen.

Here is a chicken that I purchased from my local market. It is labeled fresh and it is soft as a baby's bottom. Here is another piece of chicken that I purchased from the same supermarket, but it has been frozen to a few degrees above zero. As you can see, the frozen chicken is as hard as a rock. Under USDA's policies, both chickens are labeled as fresh. This frozen chicken could be defrosted and still be sold as fresh. But clearly one chicken is fresh and the other is frozen.

USDA's policies amount to outright consumer fraud and deception—I can't say it any other way. But the issue of what is fresh and what is frozen involves more than just honest labeling. It involves broader questions on the Federal preemption of State laws and the use of policy guidelines in lieu of rulemaking.

Recent hearings by the Human Resources and Intergovernmental Relations Subcommittee have revealed that USDA's meat and poultry programs are obsolete, misleading and incapable of protecting the public from harmful microbial contamination, the primary cause of foodborne illness in the United States of America. Yet USDA has failed to fix the fatal flaws in its inspection programs because its primary mission to promote agriculture has overshadowed its responsibility to protect the consumers.

The issue of fresh poultry once again demonstrates the institutional conflict of interest inherent within USDA. Consumers have a right to expect that the chicken they purchase is safe to eat and honestly labeled. If USDA will not protect consumers, then perhaps we should move the meat and poultry inspection programs out of USDA, as the Vice President has recommended.

The issue of undue industry influence at the Department of Agriculture regarding the poultry inspection program also has been raised. This is an important matter involving issues which can only be fully answered by the Secretary. These allegations are connected to an open criminal investigation at the Department of Justice. It would be inappropriate to have the Secretary appear before us now to discuss issues which may be the subject of a pending Justice Department probe.

The subcommittee has received a letter from the Department of Justice and the Inspector General at the Department of Agriculture requesting that the Inspector General not be requested to testify on this issue at this time. In view of the request, I do not intend to have the Inspector General testify at this time. However, I do intend to have both the Secretary and the Inspector General appear before this subcommittee at the appropriate time to discuss these issues.

I ask unanimous consent that the relevant correspondence from the Department of Justice and the Acting Inspector General at the Department of Agriculture be included in the record.

[The information referred to follows:]

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives
Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Majority (202) 225-2548
FAX (202) 225-2382
Minority (202) 225-2738

May 20, 1994

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

Dear Mr. Secretary:

In the exercise of its oversight responsibilities pursuant to Rules X and XI of the House of Representatives, the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees of the House Committee on Government Operations are jointly reviewing the U.S. Department of Agriculture's (USDA) labeling of poultry products. In furtherance of this review, we are pleased to invite you to testify at a joint hearing scheduled for Wednesday, June 8, 1994, at 9:30 a.m., in Room 2154 of the Rayburn House Office Building.

Specifically, we would like you to address:

-- the Food Safety and Inspection Service's (FSIS) regulations for "fresh" labels on raw poultry that have been shipped or stored at temperatures as low as zero degrees;

-- USDA's current review of the issue;

-- any and all USDA plans or proposals to change or otherwise modify this regulation since 1988; and

-- any and all research that USDA has conducted, sponsored or is otherwise aware of concerning the freezing temperatures of raw poultry.

In addition, we would appreciate receiving the following documents by Friday, May 27, 1994: All records written or received by agency employees--including, but not necessarily limited to, notes, memoranda, correspondence, electronically transmitted communications, and other drafts, analyses or reports--in any way related to USDA's ongoing review of regulations for "fresh" labels on raw poultry.

Because of the importance of this issue to both consumers and sellers of poultry, we believe that if you are unable to personally participate in the hearing that you designate Patricia Jensen, the Acting Assistant Secretary for Marketing and Inspection

Services, to represent the Department. We believe no other USDA official could appropriately address the fundamental public policy issues involved.

Please arrange to have 50 copies of your prepared statement delivered to the Subcommittee office (room B-372 Rayburn) by no later than 5:00 p.m., June 3, 1994. Such advance submission is required in order to give the Members an opportunity to study your statement before the hearing. Also, please bring 125 copies of your statement with you to the hearing. The typed statement should be single-spaced with two-sided copying, if possible.

You will have 10 minutes to present oral testimony. If your prepared statement will require more than 10 minutes of oral testimony, please be prepared to summarize it in approximately that time. Your entire statement will be printed in the hearing record. There will be a question and answer period with the Members at the end of your oral testimony.

I greatly appreciate your cooperation in this matter and look forward to your testimony. If you have questions, please contact Bill Layden at 202/225-2548 or Ed Armstrong at 202/225-3741.

Sincerely,

Gary A. Condit
Chairman
Information, Justice,
Transportation, and
Agriculture Subcommittee

Edolphus Towns
Chairman,
Human Resources and
Intergovernmental Affairs
Subcommittee

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives
Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Majority (202) 225-2548
FAX (202) 225-2382
Minority (202) 225-2738

June 10, 1994

Charles R. Gillum
Acting Inspector General
U.S. Department of Agriculture
Rm. 117-W ADMBG
12th and Independence Ave., S.W.
Washington, DC 20250-2301

Dear Mr. Gillum:

In the exercise of its oversight responsibilities pursuant to Rules X and XI of the House of Representatives, the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees of the House Committee on Government Operations are jointly reviewing the U.S. Department of Agriculture's (USDA) regulation and labeling of poultry products. In furtherance of this review, we are pleased to invite you to testify at a joint hearing scheduled for Thursday, June 16, 1994, at 9:30 a.m., in Room 2154 of the Rayburn House Office Building.

Specifically, we would like you to address the status and results of all investigations involving any and all USDA officials, including the Secretary of Agriculture, relating to bribery, illegal gratuities, illegal gifts, or other alleged attempts by any poultry firm or agent to influence USDA officials, policy, regulations, or enforcement actions.

Please arrange to have 50 copies of your prepared statement delivered to the Subcommittee office (room B-372 Rayburn) by no later than 5:00 p.m., June 14, 1994. Such advance submission is required in order to give the Members an opportunity to study your statement before the hearing. Also, please bring 125 copies of your statement with you to the hearing. The typed statement should be single-spaced with two-sided copying, if possible.

You will have five minutes to present oral testimony. If your prepared statement will require more than five minutes of oral testimony, please be prepared to summarize it in approximately that time. Your entire statement will be printed in the hearing record. There will be a question and answer period with the Members at the end of your oral testimony.

Mr. Gillum
June 10, 1994
Page Two

I greatly appreciate your cooperation in this matter and look forward to your testimony. If you have questions, please contact Ron Stroman or Bill Layden, of the subcommittee staff, at 202/225-2548.

Sincerely,

Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations

ET:bl

cc: The Honorable Gary A. Condit, Chairman, Subcommittee on Information, Justice, Transportation and Agriculture

The Honorable Steven Schiff, Ranking Minority Member, HRIR

The Honorable Craig Thomas, Ranking Minority Member, IJTA

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives
Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Majority (202) 225-2548
FAX (202) 225-2382
Minority (202) 225-2738

June 3, 1994

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

Dear Mr. Secretary:

As you are aware, the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees of the House Committee on Government Operations are jointly conducting a hearing on the U.S. Department of Agriculture's (USDA) labeling of frozen poultry products. This letter is to inform you that the hearing date and location have been changed to June 16, 1994, at 9:30 a.m., in Room 2167 of the Rayburn House Office Building.

Furthermore, as staff from our subcommittees discussed with representatives of your office on Tuesday, May 31, 1994, we now believe that it is important to place the issue of labeling frozen chicken products in the larger context of how USDA regulates poultry products in the United States. Thus, in addition to the issues that we asked you to address in our letter to you of May 20, we would like you to address USDA's regulation of poultry products in general, including, but necessarily limited to, (1) USDA's announced poultry enhancement program; (2) the results of Research Triangle Institute's study entitled, Comparison of USDA Meat and Poultry Regulations; and (3) the status of all pathogen reduction activities involving the safety and quality of poultry products, including the former Assistant Secretary's pledge to reevaluate the meaning and use of the USDA inspection seal.

To prepare for the hearing, we would appreciate receiving the following documents by Friday, June 10, 1994: All records written or received by agency employees--including, but not necessarily limited to, notes, memoranda, correspondence, electronically transmitted communications, and other drafts, analyses or reports--in any way related to (1) USDA's analyses and activities associated with the Research Triangle Institute's study entitled, Comparison of USDA Meat and Poultry Regulations; and (2) Policy Memo 022, "Poultry Products Labeled as 'Fresh,' 'Not Frozen,' and Similar Terms," and all revisions thereto not otherwise already provided to the subcommittees.

Please arrange to have 50 copies of your prepared statement delivered to the Subcommittee office (room B-372 Rayburn) by no later than 5:00 p.m., June 14, 1994.

Such advance submission is required in order to give the Members an opportunity to study your statement before the hearing. Also, please bring 125 copies of your statement with you to the hearing. The typed statement should be single-spaced with two-sided copying, if possible.

You will have 10 minutes to present oral testimony. If your prepared statement will require more than 10 minutes of oral testimony, please be prepared to summarize it in approximately that time. Your entire statement will be printed in the hearing record. There will be a question and answer period with the Members at the end of your oral testimony.

We greatly appreciate your cooperation in this matter and look forward to your testimony. If you have questions, please contact Bill Layden at 202/225-2548 or Ed Armstrong at 202/225-3741.

Sincerely,

Edolphus Towns
Chairman
Human Resources and
Intergovernmental Relations
Subcommittee

Gary A. Condit
Chairman
Information, Justice,
Transportation, and
Agriculture Subcommittee

cc: The Honorable Steven Schiff
The Honorable Craig Thomas
(Ranking Minority Members)

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
WASHINGTON, D C 20250

JUL 14 1994

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
U.S. House of Representatives
B372 Rayburn House Office Building
Washington, D.C. 20515-6148

Dear Mr. Chairman:

This is in reply to your letter of June 10, 1994, concerning a joint hearing of the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees, scheduled for June 16, 1994, pertaining to the U.S. Department of Agriculture's (USDA) regulation and labeling of poultry products. You invited me to testify at the hearing concerning the status and results of all investigations of USDA officials relating to bribery, receipt of illegal gifts and gratuities, and/or other attempts "by any poultry firm or agent" to influence USDA employees regarding policy, regulations or enforcement actions involving poultry.

The information you have requested has been referred to the U.S. Department of Justice for its determination whether action by that Department is warranted. After a decision by the Department of Justice and any action it may take, USDA officials, in consultation with the Department's Office of the General Counsel, will determine whether any administrative action against any business or individual or whether any disciplinary action against any USDA employee is required. In light of this, it would be inappropriate for me to make any statement or to testify concerning this matter while it is still under review.

I am sorry that I cannot be more responsive to your invitation to testify at this time, but I look forward to meeting with you and other members of the Subcommittees in the future should you so desire. If you have any additional questions concerning this issue, please feel free to call me at 720-8001 or have a member of your staff contact Craig L. Beauchamp, Assistant Inspector General for Investigations, at 720-3306.

Sincerely,

CHARLES R. GILLUM
Acting Inspector General

cc:
Honorable Gary A. Condit, Chairman,
Subcommittee on Information, Justice,
Transportation and Agriculture
Honorable Steven Schiff, Ranking Minority Member, HRIB
Honorable Craig Thomas, Ranking Minority Member, JJTA

U.S. Department of Justice

Criminal Division

Office of the Assistant Attorney General *Washington, D.C. 20530*

June 15, 1994

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Department of Justice joins in the request of the Inspector General, Department of Agriculture, that he not be requested to testify before your subcommittee at this time with respect to ongoing criminal investigations.

Sincerely,

Jo Ann Harris
Assistant Attorney General

By: John C. Keeney
John C. Keeney
Deputy Assistant Attorney

Mr. TOWNS. At this time, I would like to yield to the gentleman from California, Mr. Condit, chairman of the Information, Justice, Transportation, and Agriculture Subcommittee.

Mr. Condit.

Mr. CONDIT. Thank you.

Good morning, and I would like to begin by offering my profound thanks to Chairman Ed Towns and his staff for their cooperation and efforts in planning this hearing.

For a variety of reasons which I will explain, poultry labeling has become one of the most important agricultural issues in my home State of California: the issue of fresh versus frozen extends beyond the borders of California. However, in my opinion, it cuts from the chicken farm to the kitchen table.

In 1988, the USDA attempted to resolve this issue by issuing a policy memo 022B. This document stated that the word "fresh" may not be used in conjunction with any poultry product that has been frozen or previously frozen to 26 degrees Fahrenheit or below. I stress the standard is based on Fahrenheit scales where water freezes at 32 degrees.

This policy memo created, to say the least, an uproar. As a result of its issuance, high level poultry officials took their complaint all the way to the Secretary's Office. The unfortunate result of all this was that it ended in a complete stalemate. The industry could not agree. USDA could not govern, and the consumer was left in the dark.

Our review of this situation has uncovered no evidence that USDA ever consulted or considered consumer interest in preparing its policy on fresh versus frozen.

I have been presented with a survey prepared for the California Poultry Industry Federation that did consider consumer opinion on this issue and the results are eye opening. The charts we have on display will explain what I am talking about. A full 75 percent of more than 1,000 people surveyed felt that chicken below the temperature of 26 degrees should not be labeled fresh. In fact, 86 percent felt that it is wrong for frozen chicken to bear the label fresh.

I would ask unanimous consent, Mr. Chairman, that the results of the ICR survey be placed in the record.

Mr. TOWNS. Without objection, so ordered.

[The information referred to follows:]

AUS CONSULTANTS
ICR Survey Research Group
605 West State Street
Media PA 19063-2620
215-565-9280
FAX 215-565-2369

Labeling Previously Frozen Chicken Fresh: The Public's Assessment Topline Findings

Prepared for:
The California Poultry Industry Federation

Prepared by:
ICR Survey Research Group

Labeling Previously Frozen Chicken Fresh: The Public's Assessment
Topline Findings

Prepared for:
The California Poultry Industry Federation

Prepared by:
ICR Survey Research Group

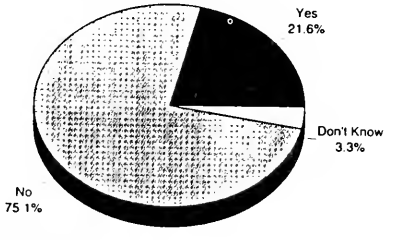
To assess public opinion regarding the public's views about the labeling as "fresh" chicken which has been chilled below a temperature (about 26° F.) where it becomes hard, a national telephone survey was conducted among the general public June 2-6, 1994.

The survey asked respondents whether chicken which has been shipped or stored below 26° F. should be called "fresh;" their views on whether it was appropriate or inappropriate to label this chicken as "fresh;" their views on the differences in overall quality, taste, tenderness and juiciness between never frozen and previously frozen chicken; and their views about the appropriate pricing of previously frozen vs. frozen chicken.

Key Findings

1. The vast majority (75%) of the public does **NOT** think chicken which has been shipped or stored below the temperature of 26° F. should be called "fresh."

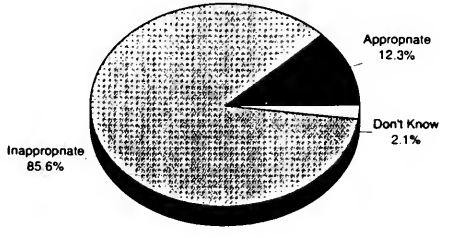
   "At between 26 and 32 degrees, chicken will feel cold but still soft to the touch. Under 26 degrees, the chicken will become hard. Do you think that chicken which has been shipped or stored below 26 degrees should be called fresh?"



Source: ICR Survey Research Group

2. The vast majority (86%) of the public thinks it is wrong to label as "fresh" chicken which has been stored below 26 ° F.

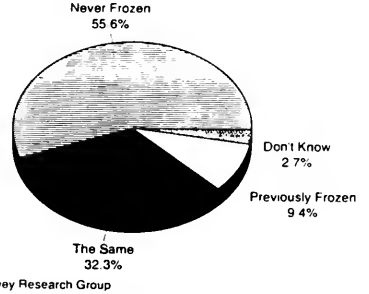
"Chicken which is stored at temperatures below 26 degrees becomes rock hard. Do you think it is appropriate or inappropriate to label as "fresh" chicken which has been stored below 26 degrees and then thawed out?"



Source: ICR Survey Research Group

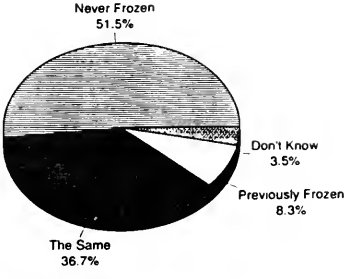
3. Four out of five (81%) consumers think there is a difference between chicken which has never been frozen and chicken which has been frozen and thawed. When asked whether chicken which has never been frozen was better, worse or the same as chicken which has been frozen and then thawed, consumers rated "never frozen" chicken as superior by a five to one margin on:

- **Overall Quality** (56% vs. 9%);



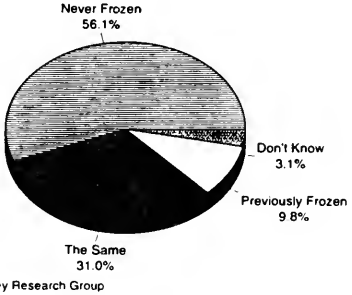
Source: ICR Survey Research Group

- **Tenderness** (52% vs. 8%);



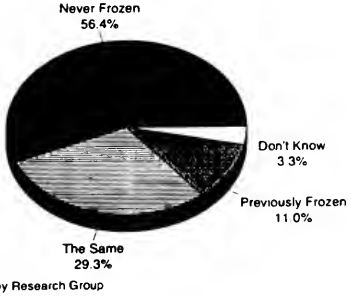
Source: ICR Survey Research Group

- **Flavor/Taste** (56% vs. 10%); and,



Source: ICR Survey Research Group

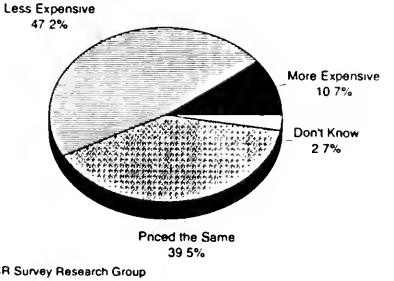
- **Juiciness** (56% vs. 11%)



Source: ICR Survey Research Group

4. The plurality of Americans (47%) think that chicken that has been frozen and then thawed should be LESS expensive than chicken that is sold frozen in the supermarket case; a somewhat smaller percentage (40%) think frozen-and-then-thawed chicken should be priced the same as frozen chicken. Only 11% of the public feels that previously frozen chicken should be more expensive then chicken that is sold frozen from the supermarket freezer case.

"Do you think that chicken that has been frozen and then thawed should be more expensive, less expensive or priced the same as chicken that is sold frozen from the supermarket freezer case"?



Source ICR Survey Research Group

Survey Methodology

The telephone survey consisted of N = 1027 interviews, 1/2 with men and 1/2 with women. The survey sample design used a fully-replicated, stratified, single-stage random digit dialing (RDD) sample of telephone households. The sampling error for a survey of this size is ± 3.16 at the 95% confidence level.

All survey interviews were conducted between June 2-6, 1994

Survey findings were weighted to provide nationally representative and projectable estimates of the adult population 18 years of age and older. The weighting process takes into account the disproportionate probabilities of household selection due to the number of separate telephone lines and the probability associated with random selection of an individual household member. Following application of the above weights, the sample is post-stratified and balanced by key demographics such as age, sex, region and education.

About ICR Survey Research Group

ICR Survey Research Group, a division of AUS Consultants, is a full service market and public opinion research firm located in Media, Pennsylvania. With a staff of over 80 professionals and approximately 300 interviewers, ICR is among the top 50 market research firms in the country.

The ICR Survey Research Group has conducted survey research on behalf of a number of federal agencies and not-for-profit organizations, including the United States Department of Agriculture, the National Cancer Institute, the U.S. Postal Service and the Institute for Highway Safety.

Mr. CONDIT. Today, we will be taking a hard look at this topic, and I greatly appreciate the many witnesses who have in some cases traveled a long distance to be with us today. Among our witnesses will be Secretary Henry Voss of the California Department of Food and Agriculture. He has worked closely with my subcommittee in the past, and I look forward to his testimony.

Chef Wolfgang Puck has also traveled from California today. We will receive an expert opinion on the culinary aspects of this issue from Mr. Puck. I appreciate his taking the time out of his busy schedule to be with us today.

I would also like to apologize to the American Meat Institute and the California Consumer Affairs Office for not being able to include them as witnesses. We simply ran out of time. But I thank them for preparing testimony, and I ask that their statements be included in the record as well, Mr. Chairman.

Mr. TOWNS. Without objection, their entire statements will be included in the record.

[The information can be found in appendix 6.]

Mr. CONDIT. When I looked at this issue several things occur to me. First of all, I think that the consumers need to have absolute confidence that government labels on products accurately reflect the status of the product. It is clear to me at best that consumers are confused about what a fresh label means to the poultry product.

I am told that the issue of spoilage will be raised today as a reason for not changing the label standards. Let me state emphatically that I do not view this as an either/or proposition. Consumers expect the products they buy are both safe and accurately labeled. I can't see any reason why we cannot resolve this. To adopt a policy that deceives consumers for their own good is simply wrong, and I also believe it sets a terrible precedent.

I would like to turn now back to the chairman. And, Mr. Chairman, I look forward to the witnesses today. And once again, I appreciate you holding this hearing.

Mr. TOWNS. Thank you very much, Mr. Condit.

At this time, I would like to yield to Mr. Schiff, the ranking member, for any remarks that he might like to make at this time.

Mr. SCHIFF. Thank you, Mr. Chairman. I will be brief because we have a number of witnesses waiting to testify. But I would like to take the time to make two points. One is a sincere congratulations to you on holding this hearing. This is one of a number of hearings that we have held on the safety of meat in the marketplace in the United States and on inspection of meat.

And we had a previous hearing, Mr. Chairman, as I am sure you recall, in which it was testified that many thousands of people die and become ill each year because of contaminated meat. And if this occurred at one place at one time each year—in other words, if there was a disaster like an earthquake which caused the same number of deaths and illnesses that occur one by one and two by two around the country from contaminated meat—this issue would have gotten much more public attention than I think it has received. So I congratulate you on furthering these hearings so that the public can be aware of what the issues are.

Second of all, Mr. Chairman, I want to go back and talk about the issue that you alluded to, just to explain to our colleagues on both sides of the aisle before the subcommittee what went back and forth on the issue of requesting the Inspector General of the Department of Agriculture to testify today.

After this hearing was already scheduled, a number of press reports were widely circulated that indicated that officials at the Department of Agriculture, including by name the Secretary of Agriculture, may have in some way taken some kind of gratuities or otherwise have ties to certain individuals and businesses in the poultry industry that could at worst constitute a violation of the Meat Inspection Act of 1907, and at best, if one can say it that way, constitute an appearance of impropriety and possibly undue influence.

I stress these are press reports. Nevertheless, they were circulated widely enough that I approached you and suggested at this hearing as we are talking about USDA inspection of poultry, that this hearing could not get complete information unless we allowed the Agriculture Department to dispel all of these rumors in the press and explain exactly what did occur.

At my request, you did ask the Inspector General of the Department of Agriculture to testify here today, and I appreciate your acknowledging my request. The Inspector General declined the request for a couple of reasons, the major one being that he was participating in a possible criminal investigation by the Department of Justice, and the Inspector General felt that because there was a pending criminal investigation that he should not testify before us today.

My view back to you was that that was an insufficient reason not to testify from the Inspector General, because the whole idea of testimony before a congressional hearing relating to a criminal investigation is, would it interfere with that criminal investigation, and that is a decision the Justice Department ought to make, not every individual who might have some contact with the Justice Department. And so I pursued the matter with you and asked for a meeting to vote to subpoena the Inspector General.

In the mean time, however, we have received the letter from the Justice Department that you alluded to, and I would like your indulgence to read it. It is one sentence long, even though it is in the public record of this hearing. It is addressed to you, and it reads: "Dear Mr. Chairman, the Department of Justice joins in the request of the Inspector General, Department of Agriculture, that he not be requested to testify before your subcommittee at this time with respect to ongoing criminal investigations."

It is signed Joanne Harris, Assistant Attorney General by name. The signature is by John C. Keeny, Deputy Assistant Attorney.

Mr. Chairman, I feel that for today's hearing, that we should accept this letter, and I agree with your conclusion not to call the Inspector General today. Certainly we in the Congress do not wish to jeopardize in any way an official investigation by the Department of Justice.

But I just want to add that it is my intention to go back to the Department of Justice and to request that they either conclude this investigation rapidly so that it is not an obstacle to a hearing by

this subcommittee or any other committee of Congress, or that they explain in detail exactly how this hearing and this testimony at this hearing would in fact jeopardize their investigation.

It seems to me that even the Department of Justice should not be able to hold up the Congress indefinitely on a one sentence letter and without offense to the signer, but at the level of a Deputy Assistant Attorney.

Nevertheless, Mr. Chairman, I think that for today I would not want to jeopardize any Federal criminal investigation. I agree with your conclusion not to call the Inspector General, and I appreciate our going ahead and hearing the witnesses on the other issues, and I yield back.

Mr. TOWNS. I would like to thank the gentleman for his statement, and we will definitely follow through as I have indicated in my opening statement.

At this time, I would like to recognize any other Members that might have an opening statement.

Congressman Mica.

Mr. MICA. Mr. Chairman, I want to take a moment to thank you and also Mr. Condit for conducting this hearing. Our subcommittee has held additional hearings on meat, poultry inspection, and also the conduct of the Department of Agriculture.

It is my hope today that this hearing will begin to show a pattern, and that is a pattern of deception. I want to say that the Department of Agriculture has been guilty of deception. I think the highest levels of the Department of Agriculture, as far as its actions are concerned, have been deceptive.

I also want to say that the labeling program under the Department of Agriculture is deceptive to the American public.

It is my hope that this hearing, and hearings that we will have in the future; will show how the American public and also the Congress have been deceived. Quite specifically, I think we need to address the questions of selective enforcement by the Department of Agriculture inspection regarding the labeling issue.

Second, I think we need to look very specifically at how the American public and the American consumer have been deceived specifically by the Department of Agriculture.

Thank you.

Mr. TOWNS. Thank you very much.

Any other opening statements from the Members?

Congressman Portman.

Mr. PORTMAN. Mr. Chairman, again, to congratulate you and Chairman Condit for holding this hearing. I think few issues are more important to the American people than the safety of their food supply. And I look forward to continuing our constructive hearings that we have had in the Towns subcommittee today, and look forward to getting to the bottom of some of these issues.

I ask unanimous consent to have a written statement be part of the record.

Mr. TOWNS. Without objection, your written statement will be included in the record.

[The prepared statement of Mr. Portman follows:]

Statement of Representative Rob Portman

on

U.S.D.A. Regulation of Poultry Products

Subcommittees on Human Resources and Intergovernmental Relations and Information, Justice Transportation and Agriculture

of the

House Government Operations Committee

June 16, 1994

Thank you, Mr. Chairmen. Thank you for holding this very important hearing today on issues concerning U.S. Department of Agriculture's (USDA) regulation of poultry products, particularly on the classification of chickens as fresh or frozen.

There are few issues more important to the citizens of our nation than the safety and wholesomeness of our food supply. The Human Resources and Intergovernmental Relations Subcommittee has held several oversight hearings on USDA enforcement of poultry industry regulations. As the Republican Members of the Subcommittee noted in our letter of June 9, 1994 to Chairman Towns, there have been numerous reports that USDA has not enforced poultry regulations with the same diligence as beef regulations. Although I regret that Secretary of Agriculture Mike Espy and Inspector General Charles Gillum refused our invitations to testify, I welcome the opportunity today to hear all the facts necessary to make a careful and thorough determination on the issues before us.

I look forward to hearing the testimony of our distinguished panel of witnesses.

Mr. TOWNS. Any other opening statements?

I would like to call our first panel, Mr. Richard Rominger, Deputy Secretary of Agriculture.

Mr. Rominger, it is the custom of this committee to ask witnesses who testify to be sworn in. So, if you would please rise so I can swear you in.

If you have any other staff members who will be giving testimony, please ask them to step forward.

Raise your right hand. Do you swear to tell the truth, the whole truth and nothing but the truth? If you do, say in the affirmative.

Mr. ROMINGER. I do.

Mr. MEDLEY. I do.

Mr. GOLDEN. I do.

Mr. TOWNS. Let the record show that the witnesses answered in the affirmative.

Thank you very much. You may be seated.

[Witnesses sworn.]

Mr. TOWNS. Again, let me thank you for coming. We have your entire statement for the record, if you just could move forward and summarize. And since you have three staff members, we will give you 10 minutes, and then after that, we would be able to raise some questions.

Mr. HORN. Mr. Chairman, could we have identification of the two staff members with the Deputy Secretary?

Mr. TOWNS. Yes.

STATEMENT OF RICHARD ROMINGER, DEPUTY SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY TERRY MEDLEY, ACTING ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, AND JOHN GOLDEN, ASSOCIATE GENERAL COUNSEL, REGULATORY AND MARKETING

Mr. ROMINGER. Thank you, Mr. Chairman.

Yes, I have with me Mr. Terry Medley, who is the Food Safety and Inspection Service as Acting Administrator.

Mr. TOWNS. Mr. Rominger, would you pull the mike a little closer to you. We are having difficulty hearing you.

Mr. ROMINGER. Sorry.

This is Mr. Terry Medley who is the Food Safety and Inspection Service Acting Administrator; and this is John Golden, who is the Associate General Counsel for Regulatory and Marketing.

Thank you, Chairman Towns, Chairman Condit, members of the subcommittee. I am here before you today to discuss the Department of Agriculture's policies regarding the regulation of poultry products. We have already sworn in the rest of the witnesses here, so I would request that my written testimony be entered into record.

Mr. TOWNS. Without objection, your entire statement will be included in the record.

Mr. ROMINGER. Thank you.

Since coming to office in January 1993, Secretary Espy has aggressively carried out his responsibilities under the Poultry Products Inspection Act to ensure that poultry products are wholesome, not adulterated and properly marked, labeled and packaged.

Some may wish to joke about some of these issues, but I think that these are serious issues. They are complex. They cannot be answered with simple sound bites. They require a careful evaluation of both science and consumer perceptions. As a result, these issues must be addressed and resolved with the seriousness and deliberation that both our Nation's consumers and the poultry industry expect and deserve.

So my oral testimony will focus on the following issues: review of the labeling of poultry products as fresh; review of the wholesome legend; the status of our pathogen reduction activities related to poultry products, and the results of the study comparing meat and poultry regulations; and finally, the Department's plans for a poultry enhancement program.

First, the fresh labeling policy. On February 10, 1994, Secretary Espy directed the Food Safety and Inspection Service to reexamine its policy for use of the term "fresh" on labels of raw poultry products. As the Secretary stated, the current labeling policy in this area should be examined to ensure that it is reasonable and meets today's consumer expectations.

However, because food safety is a top priority for the Secretary, he also directed FSIS to make sure that any policy change does not open the door to problems like to growth of bacteria that could cause foodborne illness. FSIS is currently analyzing the scientific literature and the data relative to these food safety issues. The initial scientific review is essential to this process. Consumers are not simply concerned about whether or not a food product is labeled as fresh, they also demand and deserve a safe food supply.

Currently, the Code of Federal Regulations explicitly provides that poultry may be labeled as frozen only if it is maintained at zero degrees Fahrenheit or below, and that generally poultry must be shipped at 40 degrees Fahrenheit or below. So FSIS policy for fresh is based upon these regulations. This policy has been amended several times under previous administrations as was noted earlier. So my written testimony that you have reviews those continuing changes of the fresh policy going back to 1981.

But the current policy is set forth in policy memo 022C which was issued in 1989. It is this policy that is now being reexamined by the Department, so let me provide a brief overview of the Secretary's specific objectives in this reexamination.

It is first, food safety is a priority. Any policy change must not open the door to food safety problems. FSIS staff has begun collecting and reviewing existing scientific literature on the effects of temperature on poultry. This review will be completed this month, and the information will be considered in July by the National Advisory Committee on Microbiological Criteria for Foods, known as the Micro Committee. This committee will prepare a report based on this information. And this committee is composed of 25 highly respected scientists in food safety and human health disciplines from industry, public interest groups academia and government.

Second, the Secretary asked for consumer input on their perception of fresh, and as a result, I am announcing today that FSIS will conduct a series of public hearings on this issue. These hearings will provide consumers, producers, industry, State and local government officials, health officials and all other interested parties

with the opportunity to present their views. This will include a hearing in California.

FSIS will also work directly with consumer interests to obtain their input through USDA's Office of Consumer Affairs and with the Agricultural Research Service to conduct some sensory evaluation research.

To ensure it is a well-informed, sound policy determination, upon completion of these two objectives, scientific data and consumer input will be reviewed, and the Department will then announce what action is necessary relative to this policy.

During the previous hearing, the subcommittee requested review of the "Inspected for Wholesomeness" legend. The Department understands and appreciates the chairman's concerns that a product is labeled wholesome despite the fact that pathogens may still exist on a carcass. The wholesome legend does not represent that the poultry product is sterile. Rather, it means that the product has been inspected and passed and was found at the time of inspection to be not adulterated.

However, concern regarding the existence of pathogens on the inspected birds is one reason why the Department has aggressively mandated safe handling labels on all meat and poultry products. The wholesome official legend must be reviewed in tandem with the new safe food handling label to ensure food safety and destruction of pathogens.

Recognizing the need to go even farther, the Secretary has directed a targeted pathogen reduction program. So I will mention that now.

Due to the importance of this program and its relationship to food safety, I will now address briefly the Department's pathogen reduction activities. To strengthen the inspection programs, we have adopted a pathogen reduction program, a comprehensive campaign which reaches from the farm to the table. Overall, the Department has more than 70 pathogen reduction initiatives underway. In the interest of time, I will only discuss a very few of these initiatives, emphasizing the application to poultry.

Enforcement has been a primary focus of our efforts to reduce pathogens. Secretary Espy has initiated a vigorous enforcement initiative to ensure that plants meet Federal inspection requirements.

Last fall, the Secretary ordered unannounced reviews of 1,000 plants nationwide, and as of June 1, over 400 of those reviews have been conducted. Of those reviews 69 percent were conducted in either poultry only or meat and poultry combination plants, and this represents approximately the same proportion of poultry only and meat and poultry combination plants as the total number of federally inspected plants.

When serious inspection deficiencies are found during these special reviews, plants are issued an accelerated deficiency notice, ADN. Plants receiving ADNs must immediately correct deficiencies and face more frequent reviews by the Department to ensure that appropriate corrective actions have been taken. In addition, they are required to develop and implement an effective action plan to permanently correct the problems cited in the ADN.

Since these reviews began, over 620 ADNs have been issued by the reviewers. If insufficient progress is made in correcting these

deficiencies, the plant may be placed on an enforcement plan referred to as our progressive enforcement action [PEA], an aggressive, intensified inspection program. Failure to meet requirements under this program can lead to withdrawal of inspection.

Currently, a total of 207 plants are under this intensive inspection initiative. FSIS has placed 16 poultry-only plants and 145 meat and poultry combination plants on PEA. Thus, out of the total number of plants under PEA, 161 are poultry-related plants.

FSIS also conducted a targeted review of turkey plants last fall. This review involved all 26 turkey plants operating under the new turkey inspection system and was conducted during October and November to ensure observation during peak operating periods. This review found the majority of turkey plants had few or no deficiencies.

FSIS did followup reviews in March and April, and the four plants that had either serious deficiencies or numerous procedural inconsistencies. The followup reviews found no serious deficiencies and that all the deficiencies documented in the previous reports had been corrected. Review recommendations were also incorporated into other progressive enforcement action plans.

This enforcement effort clearly illustrates the administration's aggressive commitment to strengthening the meat and poultry inspection systems. To expand these efforts even further, we pressed for funds to hire 200 additional inspectors this year, an the administration is also requesting funding to hire an additional 200 inspectors for fiscal year 1995.

The key to pathogen reduction efforts is the modernization of USDA's meat and poultry inspection program through the adoption of a hazard analysis and critical control points approach to risk-based inspection. This approach, commonly referred to as HACCP, would regulate both meat and poultry plants.

The HACCP approach involves identifying critical control points and establishing critical limits for each of those critical control points. Each critical control point must have one or more measures that must be monitored to ensure process control. These measures or critical limits can be established from either chemical or physical guidelines. Research is under way to establish microbial guidelines. These guidelines may either be currently covered by USDA regulations or may be derived from other sources.

These types of issues were discussed at the USDA sponsored HACCP roundtable held here in Washington in late March. These and other issues are being considered by FSIS as it develops a proposed rule for mandatory HACCP in meat and poultry plants.

The Department is focusing its efforts throughout the entire food chain from farm to table. So as a result, pathogen reduction efforts include preharvest activities and an on farm food safety focus.

On farm food safety activities are primarily the responsibility of the Department's Animal and Plant Health Inspection Service [APHIS]. Models for other health issues that affect meat and poultry will take some time to be developed but are critical to minimizing the existence of foodborne pathogens on the farm and preventing their spread to other points along the food chain. An integral part of developing these pathogen reduction models will be identify-

ing the critical control points and developing intervention strategies.

Microbiological testing is an important step in Secretary Espy's strategic plan. As a result, nationwide microbial baseline studies to determine the presence and levels of pathogen on meat and poultry have been launched. A microbiological survey on broiler chickens is in the trial stage now. It is expected to begin in broiler plants nationwide in July 1994.

Mr. TOWNS. Mr. Rominger, if you could summarize. Your time has expired. Could you summarize?

Mr. ROMINGER. I have a couple more pages. May I continue or not?

Mr. TOWNS. Well, I would like you to summarize, because we allowed you 10 minutes, and we would like to be able to raise some questions with you.

Mr. ROMINGER. OK. Many of these pathogen reduction tests are under way. The safe handling labels are important. We have mandated those, as you know. All meat and poultry products will have to meet those deadlines by July 6.

We have commissioned a study by the Research Triangle Institute to compare meat and poultry regulations, and that study was completed in June 1993 and found that there were minor differences, and most of those differences we can attribute to the differences in the species, to the differing industry practices when those statutes were enacted because they were enacted 51 years apart—the Meat Inspection Act in 1906 and the Poultry Products Inspection Act in 1957.

Our poultry enhancement program involves stepping up our activities in poultry inspection, and that includes reinforcing the zero tolerance policy. It includes microbial testing on statistical sampling, and other additions and improvements in our inspection program.

So I appreciate the opportunity to inform you of our aggressive program. I want to reiterate that this is a priority at the Department, and Secretary Espy and all of us at USDA are committed to ensuring that these issues receive the serious attention and review that they deserve.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Rominger follows:]

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

STATEMENT OF
MR. RICHARD ROMINGER
DEPUTY SECRETARY
U.S. DEPARTMENT OF AGRICULTURE

BEFORE THE SUBCOMMITTEES ON
INFORMATION, JUSTICE, TRANSPORTATION AND AGRICULTURE
AND
HUMAN RESOURCES AND INTERGOVERNMENTAL AFFAIRS
OF THE COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

June 16, 1994

Chairman Condit, Chairman Towns, and members of the Subcommittees, it is a pleasure to appear before you today to discuss the Department of Agriculture's policies regarding the regulation of poultry products. With me today are Mr. Terry Medley, Acting Administrator, Food Safety and Inspection Service and Mr. John Golden, Associate General Counsel for Regulatory and Marketing. I would like them to be sworn in with me as witnesses.

Since coming to office in January 1993, Secretary Espy has aggressively carried out the Department's responsibilities under the Poultry Products Inspection Act (PPIA) to ensure that poultry products are wholesome, not adulterated, and properly marked, labeled and packaged. The issue of food safety may be one in which some may wish to joke about by bowling chickens or trivializing it with various media sideshows. Despite the appeal of such events, the seriousness and complexity of food safety cannot be overlooked.

In this Administration, USDA will not play a game of pins or Russian roulette with the lives of children, the elderly, and the nation's and world's consumers. The stakes are simply too high.

The issues before the subcommittee today cannot be answered with simple "sound bites." They are complex. They require careful evaluation of both science and consumer perceptions. As a result, these issues must be addressed and resolved with the seriousness and deliberation that both our nation's consumers and the poultry industry expect and deserve.

As you requested in your letters of invitation dated May 20, 1994, and June 3, 1994, my testimony today will address the following issues: review of the labeling of poultry products as "fresh"; the results of the study comparing meat and poultry regulations; the Department's plans for the Poultry Enhancement Program; the status of pathogen reduction

activities related to poultry products; and the Department's evaluation of the USDA official inspection legend.

USDA'S FRESH LABELING POLICY

On February 10, 1994, Secretary Espy directed the Food Safety and Inspection Service (FSIS) to reexamine its policy for use of the term "fresh" on the labels of raw poultry products. As the Secretary stated, the current labeling policy in this area should be examined to ensure that it "is reasonable and meets today's consumer expectations." However, because food safety is a top priority for the Secretary, he also has directed FSIS to "make sure that any policy change does not open the door to problems like the growth of bacteria that could cause foodborne illness." See Attachment A (USDA News Release, February 10, 1994).

FSIS is actively pursuing Secretary Espy's objective to consider both the scientific bases for the policy and the consumer's perception of the term "fresh." As described below, FSIS is currently analyzing the scientific literature and data relative to these food safety issues. The initial scientific review is essential to this process not only due to the food safety implications, but also because consumers are not simply concerned with whether or not a food product is labeled as "fresh." They also demand and deserve food that is safe. FSIS also recently began its efforts to examine consumer perceptions of the term "fresh."

Background

USDA's policy on "fresh" has been amended several times since the early 1980s. The policy is based on Federal regulations that set temperatures and chilling and freezing procedures for poultry products, and regulations for the labeling of such products. Part 381 of Title 9 of the Code of Federal Regulations (CFR) explicitly provides that poultry may be labeled as "frozen" only if it is maintained at zero degrees Fahrenheit or below. These regulations further provide generally that poultry must be shipped at 40 degrees Fahrenheit or below. FSIS has interpreted these regulations to permit unprocessed poultry kept at above zero degrees Fahrenheit and at or below 40 degrees Fahrenheit to be labeled as "fresh."

Under the administration of Secretary John Block, the FSIS Director of the Standards and Labeling Division issued Policy Memo 022 on February 9, 1981. Policy Memo 022 interpreted the regulations which set temperatures and chilling and freezing procedures for poultry, and the labeling of such poultry, to allow the term "fresh" to apply to poultry products that had a thin layer of frozen surface crust caused by chilling processes, but did not allow the use of "fresh" on labels of poultry products that had been completely frozen. This memo did not include a reference to a particular temperature to separate fresh and frozen poultry products.

On May 5, 1981, the Block Administration issued Policy Memo 022A, which clarified the point of separation between fresh and frozen as zero degrees Fahrenheit. It did not allow

use of the term "fresh" on labels of poultry products that had been frozen at any time during processing.

Seven years later, in 1988, at the request of some poultry industry members, FSIS again reviewed the policy on the use of the term "fresh." On July 11, 1988, Secretary Richard Lyng's Administration issued Policy Memo 022B, which would have prohibited the use of the term "fresh" in conjunction with any poultry product that was chilled or had been previously chilled at its center or core location to 26 degrees Fahrenheit or below. Policy Memo 022B was issued by the FSIS Director of the Standards and Labeling Division under the direction of FSIS Administrator Dr. Lester Crawford. This Policy Memo noted that the proposed revision was partly based on that administration's belief that the term "fresh" on poultry products had "acquired marketing significance and offered a meaningful distinction to purchasers between frozen and never frozen products." Policy Memo 022B, although issued, was never implemented.

Six months later, on January 11, 1989, after receiving comments from some members of the poultry industry, FSIS issued Policy Memo 022C. It allowed a product to be labeled as "fresh" if it was above zero degrees Fahrenheit and at or below 40 degrees Fahrenheit, and had not been previously frozen at or below zero degrees. Policy Memo 022C was issued by the FSIS Director of the Standards and Labeling Division under the direction of FSIS Administrator Crawford.

Policy Memo 022C states that it was "predicated on the belief that it was not practical under existing marketing strategies and distribution patterns, to define 'fresh' in terms of internal temperature beyond the scope of the current regulations. . . ." This Lyng Administration Policy Memo also stated that it was "[not] practical to define consumer expectations for poultry products labeled as 'fresh.'" The memo concluded that the consumer was the best judge of preference in chilling temperatures for unprocessed poultry products labeled as "fresh," and that the marketplace was best suited for making these distinctions. Policy Memo 022C established a broad range of temperatures for which the term "fresh" could be used.

Current Policy Review

After Secretary Espy announced the review of the "fresh" labeling policy, FSIS Science and Technology and Regulatory Programs staff began collecting and reviewing existing scientific literature concerning the physiological and microbial effects on poultry of temperatures in the range of 40 degrees to 0 degrees Fahrenheit. Three areas of analysis form the scientific basis for the review:

1. the physics of poultry being chilled between the temperatures of 40 degrees to 0 degrees Fahrenheit;
2. the microbiological behavior of pathogens in the same temperature range; and

3. the microbiological behavior of spoilage organisms in the same temperature range.

The FSIS literature evaluation and resulting review will be completed this month and will be referred to the National Advisory Committee on Microbiological Criteria for Foods (Micro Committee) for peer review and comments on the facts presented and the sources used. The Micro Committee is scheduled to meet in July to complete this review and issue its comments.

The Micro Committee is an interagency advisory committee formed in 1987 in response to expectations of Congress and a recommendation by the National Academy of Sciences for an interagency approach to microbiological criteria. It serves USDA, the Food and Drug Administration, the National Marine Fisheries Service, and the Office of the Surgeon General. The Micro Committee is composed of 25 highly respected scientists in food safety and human health disciplines from industry, public interest groups, academia and government. The Committee's mission is to provide impartial scientific advice to Federal food regulatory agencies for use in the development of integrated, uniform requirements for food safety.

The Department is moving to meet the second objective in its review of the "fresh" policy. The Department will publish a notice in the Federal Register announcing a series of public hearings on the issue of labeling raw poultry products as "fresh." These hearings will provide consumers, producers, industry, state and local government officials, health officials, and all other interested parties the opportunity to present oral and written views on this issue. The hearings will be conducted by FSIS and will include a hearing in the State of California. These hearings will fulfill a very important part of Secretary Espy's policy review -- ensuring that consumers as well as all other interested parties have a voice in establishing the Department's "fresh" policy.

The Department is also utilizing the resources of the Agricultural Research Service (ARS) in its evaluation of the consumer perception of "fresh." ARS will be involved in conducting research on the sensory evaluation of "fresh" and "frozen" products. FSIS is also working with the USDA Office of Consumer Affairs to obtain additional information on consumer perceptions and input from consumer interests.

California Litigation

I would like to make several points regarding the ongoing federal court litigation in California that involves the "fresh" poultry label issue.

The National Broiler Council, the American Meat Institute, and the Arkansas Poultry Federation challenged a California law that prohibited the use of the word "fresh" on the labels of certain poultry products. In a letter to the United States Department of Justice,

United States District Judge David F. Levi specifically requested that the government file an amicus curiae brief on the question of whether the California law is preempted by federal law.

In response to Judge Levi's oral and written requests, and after USDA consulted with the Department of Justice, the government filed an amicus brief which stated that the labeling requirement in California's law was preempted by federal law. It is well established in court decisions that the federal poultry law preempts state labeling requirements that are "in addition to or, different than" federal requirements.

On April 8, 1994, the District Court issued an order which struck down the California law. The court ruled that the California law was preempted by federal law because it established a labeling requirement that was in addition to, or different than federal labeling requirements. That decision has been appealed by the defendant, Henry Voss, and the California Poultry Industry Federation, intervenor to the Ninth Circuit Court of Appeals. Consistent with the action taken in the District Court, the government also filed an amicus brief in the appellate court.

However, the government took no position on the merits of the California law, and still has not done so. In fact, the amicus briefs noted that Secretary Espy had directed that the "fresh" policy be reexamined. We want to assure the State of California and its supporters in the litigation, as well as this Committee and the public, that we are committed to reviewing the federal policy to ensure that it takes consumer perceptions into account and does not compromise food safety.

COMPARISON OF MEAT AND POULTRY REGULATIONS

In response to concerns that FSIS was not regulating meat and poultry equitably, FSIS contracted with the Research Triangle Institute (RTI) to prepare a comprehensive comparative study of the regulations issued pursuant to the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA). RTI completed and delivered its study to FSIS in June 1993. This study identified the substantive regulatory provisions which were not identical. The report also identified the significant differences and the bases for those differences. I would like to submit a copy of the Executive Summary of the RTI report for the record. (Attachment B).

The RTI report found that, while the overall goals of the two statutes and their implementing regulations were consistent -- to protect the health and welfare of consumers by assuring that meat and poultry products are wholesome, not adulterated and properly labeled -- there were many differences in the details of the regulations. RTI classified most differences as minor and directly attributable to differing language in the two statutes. Where difference existed, RTI identified three major underlying causes:

- the inherently different characteristics of the regulated species and the slaughtering and processing techniques through which they are transformed into consumer-ready products;

- differing industry practices which were in place at the time each of the statutes was enacted; and,

- the differing regulatory climates that existed at the times the two laws were enacted -- the FMIA in 1906, and the PPIA in 1957.

The RTI study proceeded to identify a list of twelve areas where the differences could be potentially significant. For purposes of clarity, FSIS combined two of the areas that concerned carcass chilling.

FSIS began to carry out activities which would minimize the identified inequities between meat and poultry inspection. Summarized below are the eleven areas of potentially significant regulatory differences and subsequent efforts to address them.

1) **Mechanically Separated Product**. The red meat product attached to bones can be recovered mechanically by crushing the bones and is subject to strict regulations that define the quality of the product, the amount of bone particles that can be included, and the amount and type of finished products that may include this material. Mechanically deboned poultry is not subject to similar regulatory restrictions. In March 1994, to address this inequity, USDA published in the Federal Register a proposal rule for red meat and an advance notice of proposed rulemaking for poultry products. The comment periods for both regulatory proposals have closed, one in May and the other in early June. The Department is evaluating the comments and expects to announce a decision regarding this item this fall.

2) **Humane Slaughter**. Statutory requirements for humane slaughter only apply to meat. However, while such requirements are not mandatory for poultry, the agency has recently completed a survey of practices in the poultry industry and found that humane methods of slaughter are widely used.

3) **Use of Skin**. Processed poultry products may include detached skin in some instances, while meat products generally cannot. However, meat slaughterers have the option of selling hide for other purposes. The real issue is whether consumers receive adequate information about products in which cheaper meat and poultry product components are substituted for skeletal muscle meat.

The mandatory use of nutrition labels on most processed meat and poultry products will be effective on August 8, 1994. This information will give the consumer detailed information on 14 nutrients including fat, saturated fat, and cholesterol. After this

nutrition information has been in the market for some period of time, the Department will evaluate whether further changes are needed.

4) **Standards of Identity or Composition**. FSIS recognizes that standards of composition have a limited future as regulatory tools. Modernization of labeling requirements in particular can be the vehicle by which these outdated requirements can be replaced so that scarce inspection resources can be better directed to higher priority public health tasks.

With the expanded nutrition label and its mandatory use on virtually all processed meat and poultry products starting this August, the Department has recognized that its current policies on standards must be changed. The Department has already taken some steps to pilot test some ideas. In May, the Meat and Poultry Advisory Committee was asked to help FSIS define some options for considering changes in these policies. FSIS is actively evaluating these options and will propose an action plan shortly.

5) **Sanitation**. Meat regulations specify that 180-degree water be used to clean equipment while poultry regulations are silent on the temperature issue. The Agency has initiated a scientific review of the best methods for removing the likely physical, chemical and microbial contamination from equipment. Findings will be applied uniformly to meat and poultry establishments.

6) **Slaughter Inspection Modernization**. Modernization of post mortem inspection procedures has proceeded more rapidly in poultry than in red meat; this trend will continue with the implementation of Poultry Enhancement Program changes. FSIS expects that analogous changes to red meat procedures can be considered in the very near future. Further, FSIS is developing a proposal to implement its mandatory HACCP regulation in all types of establishments, thus providing the basis for equity in further inspection modernization for all major species.

7) **Cooking/Heating Temperatures**. Red meat product regulations specify cooking temperatures to address certain problems associated with the products, for instance, salmonella in rare roast beef or E. coli O157:H7 in cooked patties, while poultry product regulations are either absent or less specific. FSIS and FDA scientists have recently jointly reviewed and affirmed all cooking temperature requirements to ensure consistency. The review noted that poultry cooking temperatures go well beyond the minimums necessary to achieve pathogen kill.

8) **Removal of Contamination**. Poultry regulations permit the removal of some contamination through washing with chlorinated water; no similar provisions occur in the meat regulations. In this important area, two new studies are focused on meat. The first study was funded by FSIS through a competitive mechanism administered by

USDA's Cooperative State Research Service (CSRS). This competitive process resulted in the awarding of a grant to Dr. Gary Acuff of Texas A&M. The study will:

- Compare traditional trimming, water washing, and organic acid washing for ability to remove fecal and bacterial contamination;
- Determine whether traditional trimming, water washing, and organic acid washing spread bacterial contamination; and
- Determine which of the evaluated removal procedures is superior for use in the commercial beef processing industry.

At the same time, a study is being coordinated by the National Livestock and Meat Board and carried out by five universities and several slaughter plants. The universities involved are Colorado State University, Texas A&M University, the University of Wisconsin, Iowa State University, and Kansas State University. The objectives of this study are to:

- Determine the effectiveness of manual trimming and/or automated carcass washing systems in the removal of fecal and ingesta contamination; and
- Evaluate the effectiveness of interventions (hot water, ozonated water, and hydrogen peroxide) in improving the microbiological and visual profiles of beef carcasses.

The data from both studies is expected later this calendar year.

9) **Carcass Chilling Procedures**. Meat is chilled by cold air while poultry is usually chilled by cold water and ice. To accommodate this practice, poultry regulations permit the absorption of 8% and more of water. FSIS has initiated a reevaluation of policies and practices in both red meat and poultry in this area.

10) **Exemptions**. Exempted practices defined in the PPIA are more extensive than those permitted under the FMIA. RTI has completed another major study for FSIS which reviews exemption practices. FSIS is evaluating this study to determine what actions are appropriate.

11) **Moisture Limitations in Processed Products**. FSIS is evaluating its policy on moisture limitations in the light of the new nutrition regulations that will be effective on August 8, 1994. As previously noted, the nutrition facts panel requires 14 nutrients be listed that include the amount of fat, saturated fat, cholesterol, and protein. Moisture limitations were originally designed to prevent adulteration of the product with water. FSIS is evaluating the moisture policy in conjunction with this review of standards of identity or composition.

This provides an overview, as you requested, of the RTI study and the actions being taken by FSIS in this regard.

POULTRY ENHANCEMENT PROGRAM

On March 9, 1994, Secretary Espy announced the Department's intent to further enhance and strengthen the poultry inspection system with a multi-faceted regulatory proposal. The Secretary's announcement, referred to as the Poultry Enhancement Program (PEP), included specific steps to further incorporate science and new technologies into the existing inspection systems. See Attachment C (USDA News Release, March 9, 1994). Several elements include:

- A zero tolerance policy will be enforced for poultry which requires that there be no fecal matter on product entering consumer distribution channels.

- Change in the poultry inspection sequence. The proposal calls for the inspection of poultry products to take place both before and after the internal organs are removed. This will ensure that the carcasses are examined after a key point of potential contamination (organ removal) and before the chiller.

- The poultry industry will be required to use FDA- and FSIS-approved antimicrobial rinses that reduce overall bacterial levels on raw poultry products.

- Fecal-contaminated poultry carcasses will be allowed to be washed inside and outside, rather than trimmed, if washing procedure is effective. However, all reprocessed poultry carcasses will be required to be reinspected rather than the current process which allows a sampling of carcasses to be reinspected. This move is based on a 1993 study which reconfirms the efficacy of washing.

The PEP proposed rule is presently in the review and clearance process. Interagency clearance and publication in the Federal Register are expected soon. The complexity and breadth of the proposed rule is extensive. As a result, completion of the rule has not been accomplished as quickly as the Secretary directed.

In addition, negotiations with the unionized inspection force are legally mandated prior to the adoption and implementation of inspection program changes which would impact working conditions. Although informal discussions have been ongoing during the formulation of this proposal, impact bargaining or formal negotiations have not yet occurred. FSIS will conduct impact bargaining before it pilot tests or implement the changes.

The Secretary's announcement included:

- Reconfiguration of inspector tasks and locations so that poultry carcasses can be checked after both evisceration and viscera harvest, two instrumental points at

which contamination may occur. This reconfiguration will facilitate the future implementation of mandatory microbial testing.

- Reinspection of 100% of reprocessed carcasses; and

- Introduction of a requirement that all poultry processing lines include an approved anti-bacterial treatment before the carcasses enter the chiller.

The Poultry Enhancement Program would result in significant, fundamental changes to poultry inspection including replacing the four current systems of poultry inspection with a single, more efficient system.

The Department strongly encourages all interested parties to comment on the proposed rule during the proposed 90-day comment period. This input will be carefully reviewed by the FSIS as they develop a final rule. Implementation of a final Poultry Enhancement regulation will be one of many actions the Secretary has taken to strengthen the meat and poultry inspection programs.

PATHOGEN REDUCTION ACTIVITIES

The control of pathogenic microorganisms is and always has been the implicit goal of the meat and poultry inspection program. The program has worked to achieve this goal through such activities as continuous organoleptic inspection in slaughterhouses, daily monitoring of operations in processing plants, laboratory analyses, and consumer education. However, as we all learned after the tragedy that occurred in Washington State, more had to be done to improve the safety of meat and poultry products.

In response to this challenge Secretary Espy directed the FSIS to develop a strategic pathogen reduction plan. The plan, which was provided to Congress, is based on Hazard Analysis and Critical Control Point (HACCP) principles and provides the framework for achieving our goal of improving the meat inspection program. Under the HACCP approach, the agency identified several critical areas where resources should be targeted, including live animal activities, slaughter plant activities, processing plant activities, food service and retailer activities, and consumer education. The plan also identifies where the Department needs to target its food safety research in order to support these activities. In order to maintain a systems approach that integrates and focuses the many resources within the Department, including research, inspection, and education we created the Pathogen Reduction Task Force. The Task Force is continuing the assessment of USDA program operations to improve meat and poultry inspection that Secretary Espy set into motion over one year ago. This comprehensive and ongoing approach ensures that corrective action will be taken at each step throughout the production and distribution system.

The Secretary has moved quickly and aggressively to implement the Pathogen Reduction Plan and gains have been made. At this time, I would like to provide for the record an updated report that identifies the actions we have taken to implement the Secretary's plan and the status of each one. A similar report was provided to the Committee in March. In addition, our budgets for 1993 through 1995 included the funds necessary for hiring inspectors, training, developing rapid testing methods, evaluating of process control techniques for reducing or eliminating pathogens, and research. As indicated in the report, many of the activities have been completed. However, at this time, I would like to discuss some of the major actions we have taken.

Enforcement

FSIS has increased enforcement of sanitation and other food safety requirements. As you know, Secretary Espy directed the FSIS Review and Assessment Office to begin a series of unannounced meat and poultry reviews last fall. As of June 1, 435 reviews had been completed, of which 69% were either poultry only or meat and poultry combination plants. This represents approximately the same proportion of poultry only and meat and poultry combination plants in the total number of FSIS inspected plants.

Federally inspected poultry only and meat and poultry combination plants have received an almost proportional amount of Accelerated Deficiency Notices (ADNs) issued since October 1, 1993 by the FSIS special review teams (approximately 70%). ADNs, which are written notices issued by the FSIS Review and Assessment Office, notify FSIS inspection officials when reviewers find serious food safety problems in federally inspected establishments. Plants must then immediately correct the problems cited in the ADN. Plants receiving an ADN will also receive a letter from the FSIS Deputy Administrator, Inspection Operations, requiring the plant to develop an effective Action Plan within three days. This Action Plan involves steps to permanently correct the problems cited in the ADN. The plants receiving an ADN are reviewed more frequently by FSIS inspection personnel to assure appropriate corrective action has been taken. If plants fail to make acceptable progress and corrective action, the plant may be placed on an aggressive enforcement plan referred to as Progressive Enforcement Action (PEA). PEA is an intensified inspection program that is put into place when an establishment is not consistently meeting USDA inspection requirements. PEA consists of three steps, each of which is an escalating program of intensive enforcement. Failure to comply with this PEA plan and to correct deficiencies can lead to withdrawal of inspection. Failure to comply with this PEA plan and to correct deficiencies can lead to withdrawal of inspection.

Currently, a <u>total</u> of 207 federally inspected establishments are on PEA. FSIS has placed 16 poultry only plants under Progressive Enforcement Action. Additionally, FSIS has placed 145 meat and poultry combination plants on PEA. Thus, a total of 161 plants, or 78% conducting poultry activities, are operating subject to PEA.

FSIS also conducted a targeted review of turkey plants last Fall. This review involved all 26 plants operating under the New Turkey Inspection System (NTIS) and was conducted during October and November to ensure observation during peak operating periods. This review found that the majority of turkey plants had few or no deficiencies. As with reviews for meat and other poultry plants, immediate action was taken by FSIS inspectors in these turkey plants when serious public health hazards were identified. Review recommendations have been incorporated into plans for the Poultry Enhancement Program. For example, the review recommended tightening Finished Product Standards and improving monitoring of plant quality control.

The FSIS Review and Assessment Office conducted unannounced, comprehensive follow up reviews at four of these plants in March and April 1994. During the Fall reviews, three of these plants had serious deficiencies and one had numerous variations in procedures. The results of the follow up reviews found no serious deficiencies in the NTIS Programs at these plants. Further, all deficiencies documented in the previous review reports had been corrected. The FSIS review team observed that quality control and production officials at the plants were assuming responsibility for properly monitoring the NTIS program and producing products in full compliance with the current finished product standards.

HACCP

In May 1993, Secretary Espy announced his intention to mandate Hazard Analysis and Critical Control Point (HACCP) systems in all meat and poultry plants. Modernization of USDA's meat and poultry inspection program will emphasize risk-based inspection. Both meat and poultry plants would be subject to mandatory HACCP. The HACCP approach involves identifying critical control points and establishing critical limits for each critical control point. Each critical control point must have one or more measures that must be monitored to assure process control. These measures, or critical limits, can be established from either chemical or physical guidelines. Research is underway to establish microbial guidelines. These guidelines may either be currently covered by USDA regulation, or may be derived from other sources. These issues were rigorously discussed at the USDA sponsored HACCP Round Table held in Washington in late March. Information from this meeting is being considered by FSIS as it develops a proposed rule for mandatory HACCP in meat and poultry plants.

Live Animal Activities

Our focus is not only on the slaughter and processing plants; it also includes the entire food chain from farm to table. For this reason, the Pathogen Reduction Program includes an on-farm food safety focus. On-farm food safety activities are primarily the responsibility of the Department's Animal and Plant Health Inspection Service (APHIS).

In April, APHIS held the first meeting dedicated to exploring the myriad program options that fall under preharvest food safety. Those in attendance included representatives

from industry, trade associations, universities, consumer advocacy groups, state government, CDC, FDA, and several USDA agencies. APHIS personnel already conduct animal health surveillance, disease control, and eradication missions. Such activities are already occurring on the farm, in transport, and at livestock markets and auctions.

One important outcome of this meeting was the formation of a project team assigned to coordinate and implement fiscal year 1995 activities and develop the strategic and operational action plans for APHIS for the next 2 to 3 years. By evaluating what we have done up to this point, working closely with industry on quality assurance initiatives, and cooperating with universities to develop research priorities, the team will design specific goals, objectives and activities for the coming years. APHIS hopes to implement these strategies quickly at the beginning of FY 1995. FY 1995 is the first year for which USDA has requested line-item appropriations for preharvest food safety activities.

One of our future goals, and the core of APHIS' involvement in preharvest food safety, is the development of pathogen reduction models for use on the farm. APHIS' work on Salmonella enteritidis (SE), another bacteria that causes foodborne illness, serves as a potential model for other preharvest programs. Under the SE traceback program, poultry flocks implicated in human outbreaks of SE are placed under restriction until the status of the flock is determined. While under restriction, eggs can only go to plants for processing; they cannot be marketed as table eggs. If the house is determined to be infected, restrictions remain in place until the flock is negative to appropriate tests.

Models for other health issues that affect meat and poultry will take some time to be developed, but are critical to minimizing the existence of foodborne pathogens on the farm, and preventing their spread to other points along the food chain. An integral part of developing these pathogen reduction models will be identifying critical control points and developing intervention strategies to address the problems most likely to occur.

Microbiological Testing

An important step in the Department's Strategic Plan was to launch nationwide, microbial baseline studies to determine the presence and levels of pathogens on meat and poultry. These profiles will give USDA critical yardsticks against which to measure progress to reduce risks associated with microbial contaminants. The data may also be useful in enabling scientists to isolate particular problem areas by species, location, seasonal conditions, and other factors.

A microbiological survey on broiler chickens is expected to begin in broiler plants nationwide in July 1994. The survey will run for a minimum of one year. We anticipate a report being issued in November 1995.

As with the surveys the Department is conducting on beef, samples in the broiler survey will be collected after carcass chilling, which is the end point of slaughter and dressing

operations. The organisms we will be looking for will be those most often associated with human illness as determined by foodborne illness reports or certain pathogens of concern because of the severity of the illness they produce in humans. Examples of pathogens we will be looking for in broilers include Salmonella, campylobacter, and E. coli 0157:H7. Data on organisms thought to be of value as indicators of general hygiene or process sufficiency will also be collected.

Rapid detection of microbial contamination on meat and poultry products could provide USDA a useful tool for improving meat and poultry inspection. In a Federal Register notice of October 21, 1993, FSIS described how it would evaluate test kits and specified the performance criteria considered necessary for in-plant rapid methods. In a Commerce Business Daily (CBD) solicitation of November 19, 1993, FSIS identified the technologies which it considered most promising and requested that companies working with these technologies to advise the Agency how their work could be best applied.

Also, in a series of Requests for Proposals (RFP) appearing in the CBD beginning March 24, 1994, FSIS sought competitive bids for work in these areas. Fundamentally, FSIS needs technologies, particularly rapid read-out technologies, that can be used by Agency inspectors in a plant to measure bacterial counts on equipment, instruments, surfaces and product. However, because biohazards still exist in the enrichment process needed to produce detectable levels of organisms, in-laboratory technology is also being considered.

Using bioluminescence technology as an example of USDA research in this area, USDA's Agricultural Research Service (ARS) has developed a rapid test at its Clay Center, Nebraska, laboratory. The bioluminescence technology is currently being evaluated to determine the effectiveness of the test in determining the hygiene of facilities and equipment and the biological load carried on products. ARS' Adenosine Triphosphate (ATP) bioluminescence test is designed to be an accurate and repeatable method to detect within 5 minutes relatively high levels of generic bacteria on carcasses and may be able to replace the 48 hour plate culture test currently used in laboratories to determine bacterial levels.

FSIS is also proceeding with a program to introduce microbial testing at three key places in the meat and poultry inspection process:

1. as part of pre-operational sanitation;
2. as part of slaughter inspection; and
3. as a more widely used control on ready-to-eat products.

Each element of this overall program is proceeding through trial, broad-scale pilot and implementation phases. The meat and poultry slaughter inspection microbial testing will be conducted in conjunction with the clean carcass organoleptic checks that are performed before product moves into chillers. When the clean carcass organoleptic checkpoint is implemented for poultry processing, the introduction of microbial sampling can begin.

Research

Research activities on pathogens have involved both meat and poultry. As the research agency of USDA responding to the needs of FSIS, ARS is developing Spectral Radiometry, a machine vision method, as an on-line inspection tool for poultry inspection. The objective of the project is to develop a real-time, efficient system capable of detecting abnormal poultry carcasses, based on their spectral characteristics at ultraviolet, visible, and near-infrared wavelengths. They are also planning to study the feasibility of rapid detection of salmonella with optical techniques.

Additional work is being done by researchers at Georgia Tech to identify condemnable poultry carcasses based on their differing absorption of various wavelengths of light. Their efforts include detection of visible fecal contamination and aesthetic nonconformances such as bruises and broken bones. Imaging using infrared light or other combinations of light wavelengths has the potential to allow machine vision technology to detect nonconformances that may not be seen in visible light.

Resource Requirements

Obviously, the achievement of the kinds of significant improvements envisioned by Secretary Espy for the meat and poultry inspection system will not occur unless we can provide the necessary budgetary resources. At the Secretary's direction, the Department has worked hard to identify those resources. For instance, we have provided staffing increases for FSIS. Two hundred additional inspectors have been hired during FY 1994 consistent with the Department's budget request and the approval of the Congress. Funding for an additional 200 inspectors has been requested as part of the FY 1995 budget. As you know, the Department is in the midst of a substantial effort to reorganize and downsize its activities. FSIS is the only one of the USDA's current 43 constituent agencies which is targeted for staffing increases during the next several years. This action alone emphasizes the priority the Department has given to the needs in this area. In addition, the Department has requested funding to strengthen its research activities, including a $10 million increase in the FY 1995 budget for ARS in order to greatly strengthen that agency's research efforts in support of production systems to control pathogens, and more efficient systems to detect hazardous bacteria during the slaughtering and processing of meat and poultry products. We were disappointed to learn that the House Appropriations Committee was unable to provide this requested increase within its budget allocation, but we will be working with the Congress throughout the remainder of the budget process to try to obtain the necessary funding for this important priority.

EXAMINATION OF THE WHOLESOMENESS SEAL

Since former Assistant Secretary Branstool appeared before the Subcommittee on Human Resources and Intergovernmental Affairs last November 19, FSIS has reexamined its

use of the official inspection legend, "Inspected for Wholesomeness," which appears on Federally inspected poultry products.

The official inspection legend or mark shows that an article was "inspected for wholesomeness" by USDA and indicates the official establishment number of the plant at which the product was prepared. The term means that the poultry product bearing the legend has been inspected and passed and was found at the time of inspection to be not adulterated.

However, the legend does not represent that the poultry product is sterile and completely free of pathogens. It is not a warranty against mishandling and improper cooking. Further, it does not guarantee it will remain wholesome after it leaves the Federally inspected establishment. Rather, it indicates that if properly stored, properly handled, and properly cooked, the product can be safely consumed. In other words, and I emphasize, the legend should be read in close tandem with the new USDA safe food handling labels adopted and mandated by this Department.

I would also like to point out that all mammals -- chickens, cows, dogs, cats and human beings -- can carry E. coli and other strains of potentially harmful bacteria. These bacteria are living organisms that, given the proper conditions, can reproduce quite rapidly. Under some conditions, they may reproduce in quantities significant enough to cause foodborne illness.

Secretary Espy also has mandated the new safe food handling labels on all raw meat products, including poultry. These labels help consumers avoid foodborne illness by providing comprehensive, accessible instructions on safe handling and preparation. The official inspection legend, "Inspected for Wholesomeness," should be viewed in tandem with the new safe food handling labels.

CONCLUSION

Chairmen and members of the Subcommittees, I appreciate the opportunity to inform you of the Department's aggressive programs and policies on improving meat and poultry inspection. I want to reiterate that this is a priority at the Department. Secretary Espy and all of us at USDA are committed to ensuring that these issues receive the serious attention and review that they deserve.

The profound questions and issues before the Committee today should not be trivialized with simplistic answers. Wrong answers can be deadly. To ignore the serious and complex nature of food safety dishonors the parents who have lost children. Political and media pressure will not determine USDA policy on these important issues. Rather, USDA will resolve these issues and design its regulatory programs through careful and deliberate consideration of the needs and expectations of the consumer, as well as the views of other interested parties, and consistent with sound scientific principles.

Thank you. This concludes my statement. I would be happy to answer any questions you may have at this time.

ATTACHMENT A

NEWS

United States Department of Agriculture | Office of Public Affairs | News Division Room 404-A Washington D.C. 20250

Release No. 0116.94

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USDA SEEKS TO REEVALUATE POLICY FOR USE OF "FRESH" ON LABELS

WASHINGTON, Feb. 10 -- Agriculture Secretary Mike Espy today announced that he has directed USDA to reexamine its policy for use of the term "fresh" on poultry product labels.

"USDA should examine whether its current policy is reasonable and meets today's consumer expectations," Espy said.

Espy noted that the state of California recently enacted a state law restricting the use of the term "fresh" to poultry that has never been at or below 25 degrees Fahrenheit. The current USDA policy permits a company to label poultry as "fresh" if it has never been at or below zero degrees Fahrenheit.

Federal preemption authority granted in the federal poultry inspection law does not permit states to impose labeling requirements that are different than or in addition to requirements set by the federal government. Three organizations filed a lawsuit to prevent the California law from going into effect. A federal judge has temporarily stopped enforcement of the law, and asked USDA to advise the court on federal law and policy.

Espy has directed the Food Safety and Inspection Service to reexamine its policy.

"I want to make sure consumers get the information and safety protections they have the right to expect whenever they buy raw poultry products," Espy said.

"Because my top priority is to increase the safety of meat and poultry products, we must also make sure that any policy change does not open the door to problems like the growth of bacteria that could cause foodborne illness," Espy said.

Secretary Espy said he is committed to seeing that USDA's evaluation of its current policy includes all concerned parties, such as consumers, producers, industry and states.

USDA is responsible for approving all labels on meat and poultry products. During the last year USDA reviewed over 200,000 labels.

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ATTACHMENT B

RESEARCH TRIANGLE INSTITUTE

June 1993

Comparison of USDA Meat and Poultry Regulations

Title 9 CFR: Subchapter A, Subchapter C

Summary Report

Submitted to
Julie Adams
Procurement and Contracting Section
U.S. Department of Agriculture
Food Safety and Inspection Service
Contracting, Room 0152
14th & Independence Avenue, SW
Washington, DC 20250

Contract No. 53-3A94-3-03
Delivery Order No. 1
Quantitative Program Evaluation Services

RTI Project No. 5461-1

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Contract No.
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Comparison of USDA Meat and Poultry Regulations

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FIGURE

COMPARISON OF MEAT AND POULTRY REGULATIONS (SUMMARY REPORT)

BACKGROUND

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for inspecting all meat and poultry products shipped in interstate commerce and for assuring consumers that meat and poultry products are wholesome; not adulterated; and are properly marked, labeled, and packaged. The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), both as amended, provide USDA this mandate. FSIS administers and reviews inspection activities to ensure that the agency's policies and regulations are consistent with the FMIA and PPIA.

Industry representatives have expressed concerns that differences in USDA regulations for meat and poultry inspection may benefit or harm one segment of the industry or the other. In response, the FSIS Administrator requested a comprehensive comparison of the meat and poultry regulations to identify and describe significant requirement differences. Consequently, Research Triangle Institute and three independent consultants (hereafter RTI) reviewed Title 9, *Code of Federal Regulations*, Subchapters A (Mandatory Meat Inspection [Parts 301-335]) and C (Mandatory Poultry Products Inspection [Part 381])[1] to identify all substantive regulatory requirements not already identical, outline the significant differences by specie, and classify the bases for those significant differences. The purpose of this report is to document RTI's findings and to outline its method of evaluation regarding this comprehensive regulatory comparison.

FINDINGS

In general, the regulations covering meat and poultry have been designed with the same intent—to protect "the health and welfare of consumers by assuring that meat and meat food products [or poultry products] are wholesome, not adulterated, and properly marked, labeled, and packaged" (p.1139)[2] . However, although the intent of the regulations remains the same, the actual requirements are quite different. This is to be expected considering that the regulated species have inherently different characteristics. These different characteristics were considered as the rules and regulations evolved. The regulations contain and present the means for effectively accommodating those differences as the respective meat and poultry industries go about challenges of converting raw materials into foods for humans and into other byproducts (e.g., pet food).

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[1] 9 CFR Parts 301-335, and 381, respectively; Revised as of January 1, 1992, with ancillaries.
[2] 21 U.S.C. § 602 and § 451.

It is within this context that we attempted to outline the differences that currently exist between the meat and poultry regulations and to classify the bases for those differences. RTI applied a "general acceptance" rule in making its determinations. If RTI judged that objective and knowledgeable professionals would generally agree on the identification and classification of the regulatory differences found, then our findings were stated accordingly. Industry was not consulted, nor were cost evaluations conducted for determination of minor vs. significant differences. Furthermore, RTI did not attempt to justify the regulatory differences found. The following is the summary of our findings.

Minor Regulatory Differences In General

The meat and poultry regulations contain hundreds of differences in regulatory requirements. Most of these differences were identified as "minor." Most of these "minor" regulatory differences are based on language variations (e.g., poultry regulations generally are shorter and more concise than are those for meat). These variations probably developed as a result of the time differential between regulatory enactment of the FMIA (1907) and the PPIA (1957).

Regulatory differences are deemed "minor" when the intent of the regulation is essentially the same and in RTI's opinion there is no identifiable difference between the burdens imposed on meat and poultry producers. These differences are denoted in the main report document as "minor," and no bases for these differences are given.

Significant Regulatory Differences in General

The regulations also reflect a number of significant regulatory differences that stem primarily from inherent differences in the two industries. First, the species slaughtered and processed are different, and they have different diseases and conditions. Thus, the procedures, processes, and equipment used to obtain consumer-ready products vary considerably between meat and poultry species. Differences of this type are outlined in the Appendix and are noted as being primarily based on inherent specie differences, which require variations in slaughter, processing, inspection, and labeling methods to ensure wholesome, nonadulterated products.

Second, the poultry industry had been growing and expanding under voluntary poultry inspection for many years prior to the mandatory Federal legislation of 1957. When the regulations were written for mandatory poultry inspection, customary and usual industry practices and standards of the time were incorporated into the regulations. Consequently, poultry regulations that are similar in subject category to meat regulations (e.g., standards of identity) reflect differences in "traditional" industry practices that continue today (e.g., "chili con carne"

must have a minimum of 40 percent fresh meat; "(poultry) chili" must have a minimum of 28 percent cooked, deboned meat). Differences of this nature are outlined in the Appendix, and the basis for these differences are classified as "traditional" (i.e., "traditional" industry practices were included in the regulatory language at the time of codification).

Finally, the poultry regulations in some parts contain very detailed requirements while the counterpart meat regulations are very general in content. This can be attributed largely to the fifty or so years difference in the ages of the FMIA and the PPIA. The meat inspection program evolved mostly during a period when policies and procedures were published in directives, manuals, and similar publications. The more recent poultry inspection program was developed mostly during a period when policies and procedures were promulgated by rulemaking, to permit public comment and better public notice consistent with the Administrative Procedure Act. (It should be noted, however, that in the last decade or so Federal agencies were discouraged from issuing new regulations, leading to a return to greater reliance on directives and policy guidance issued directly by FSIS for both meat and poultry inspection matters). It can be argued that such differences are also attributable to larger, more drastic technological and marketing changes occurring in the poultry industry in recent decades than in the red meat industry, leading to greater need for poultry inspection procedures to change and adapt. These differences have been outlined in the Appendix and their basis for differences identified primarily as "historical."

These specie, traditional, and historical-based regulatory requirement differences are deemed "significant" in that they are not "minor" differences (i.e., the potential burden on producers for such regulations may be greater on one industry or another). These "significant" differences are outlined in the report and the basis for those differences are given.

Specific Significant Regulatory Differences

Although most regulatory differences between meat and poultry are minor and/or of no real consequence to either the meat or poultry industries, there was a general agreement at RTI and among its consultants that a small number of differences may be viewed as potentially significant in terms of cost advantage to one industry or another (or to FSIS in terms of the relative costs of administering the two regulatory programs). Again, these differences identified reflect the judgment and consensus of RTI; industry was not consulted, nor were cost evaluations done. These specific significant differences are outlined below by subject area. In addition, the Appendix page numbers and CFR citation references are given for ease in locating each difference.

1. **Carcass Chilling Procedures**

Traditional chilling methods for meat and poultry carcasses are different. Meat is chilled by exposing it to cold air. Poultry chilling by cold air and by cold water immersion are both permitted. Poultry carcasses normally are immersed in chilled water and ice. The immersion chilling method for poultry allows for the absorption of 8 percent or more of water by weight into the poultry carcass, a gain in carcass weight that dry chilling methods do not impart to livestock carcasses. Livestock carcasses may be sprayed while being chilled, but are not permitted to gain weight in the process. The basis for these differences is primarily traditional (i.e., current industry practices written into the regulations at the time of codification).

Page No.	Meat CFR	Poultry CFR
F-10 to F-15	none	§ 381.66(d)(1)-(6)

2. **Humane Slaughter**

There exist regulatory requirements—with their related procedures, controls, and penalties—for the humane slaughter of livestock. There are no corresponding laws or regulations for poultry. The basis for these differences is statutory (i.e., requirements for humane slaughter of livestock are contained in the FMIA; no comparable requirements for the humane slaughter of poultry are included in the PPIA). (See 21 U.S.C. § 603[b], 610[b].)

Page No.	Meat CFR	Poultry CFR
I-1 to I-12	§ 313.1	none
	§ 313.2	none
	§ 313.5	none
	§ 313.15	none
	§ 313.16	none
	§ 313.30	none
	§ 313.50	none

3. **Poultry Reprocessing**

Carcasses contaminated on the slaughter floor are considered adulterated. Poultry carcasses may be reprocessed by washing of contaminated areas with chlorinated water; poultry regulations allow for such reprocessing and provide for equipment and procedures to accomplish it. Contaminated meat may not be washed. Trimming of contaminated areas is the only accepted method for removal of ingesta or fecal materials from livestock carcasses. The PPIA expressly permits reprocessing of poultry; the FMIA has no such provision. (See 21 U.S.C. § 455[c].)

Page No.	Meat CFR	Poultry CFR
H-27 to H-28	none	§ 381.91(b)(1)-(2)

4. Poultry Slaughter Modernization

Certain regulations that provide for new poultry inspection procedures, responding to the modernization of poultry slaughter technologies, could have comparable applications to livestock slaughter but have not been adopted in meat post-mortem inspection. These include:

a) The use of quality control (QC) concepts and cumulative sum (CUSUM) in establishing and controlling product nonconformities.

b) Plant-operated QC programs and personnel for the purpose of attaining maximum production potential.

c) Finished Product Standards (FPS) published in the regulations.

The basis for these differences is essentially "unknown" (i.e., these procedures could, with modification, be done for meat species the same as for poultry species).

Page No.	Meat CFR	Poultry CFR
G-23 to G-24	none	§ 381.76(b)(3)(i)(a) -(d), (g), (h)
G-28 to G-50	none	§ 381.76(b)(3)(iv)(c)+

5. Exemptions

Generally, the regulatory exemptions from inspection are more liberal for poultry than for meat. For instance, the meat regulations permit the uninspected slaughter and processing of livestock for household use only, but the poultry regulations permit the uninspected slaughter, processing, and sale of limited quantities of poultry and poultry products to consumers. In addition, the poultry regulations exempt from inspection certain products containing small amounts of poultry that would otherwise receive inspection under the meat regulations. The basis for most of the exemption differences is statutory. (See 21 U.S.C. § 464 and § 623.)

Page No.	Meat CFR	Poultry CFR
A-4	§ 303.1(d)(2)(i)(c)	§ 381.10(d)(2)(i)
A-19	none	§ 381.10(a)(1)
A-20	none	§ 381.10(a)(5)
A-21	none	§ 381.10(a)(6), (a)(7)
A-22	none	§ 381.10(a)(7)(b), (c)
A-22	none	§ 381.11(a)
A-23	none	§ 381.12

6. Sanitation

The meat regulations require the mandatory use of 180° F water to clean and disinfect slaughter equipment in many instances. There are no such requirements in poultry. The basis for this differences is "unknown."

Page No.	Meat CFR	Poultry CFR
D-4	§ 308.3(d)(4)	§ 381.50(b)
D-12	§ 308.8(c)	§ 381.58(a)

7. Mechanically Separated Product

Mechanically Separated (Species) (MS[S]) meat product conforming to prescribed compositional standards is permitted to be used in limited quantities in certain products. Label and use restrictions are required, along with calcium content testing and labeling. A QC program is necessary for a plant to produce MS(S). Mechanically separated poultry (MSP), a comparable product, is permitted to be used in unlimited quantities in poultry products and labeled as chicken or turkey. Bone content is the only compositional standard required. A court decision declaring that mechanically separated meat product is not "meat," coupled with relatively quick, large-scale introduction of MSP into various poultry products, appear to be the primary bases for these regulatory differences.

Page No.	Meat CFR	Poultry CFR
L-75	§ 318.18	none
M-2	§ 319.5(a)	§ 381.117(d)
M-3	§ 319.15(c)	§ 381.160
M-4	§ 319.300	§ 381.167
M-5	§ 319.301	§ 381.167
	§ 319.302	§ 381.167
	§ 319.304	§ 381.167
M-6	§ 319.305	§ 381.167
	§ 319.311	§ 381.167
	§ 319.312	§ 381.167
M-8 to M-10	§ 319.5(e)(1)-(2)	none
M-10 to M-11	§ 319.6	none
M-17	§ 319.105(b)	none

8. Cooking Temperatures

There exist regulatory requirements (and attendant controls and procedures that go with them) concerning time/temperature cooking relationships for the control of salmonella in beef, and for the control of trichina in pork. There is not a similar approach to cooking poultry rolls, which only require cooking to 160° F, or to 155° F if cured and smoked. The basis for these differences is that certain meat products are eaten "rare" by consumers; poultry products are generally not eaten "rare."

Page No.	Meat CFR	Poultry CFR
L-35 to L-36	§ 318.17(a)-(c)(3)	§ 381.150
L-71 to L-75	§ 318.17(d)(1)-(k)	none

9. Use of Skin

The poultry regulations provide that poultry carcasses, cuts, and products may contain skin. The percentage permitted ranges from 8 to 20 percent (natural proportions) and may be added to the product without label declaration. In meat, pork jowls with attached skin is permitted in processed products with a proper label declaration. Detached skin is not permitted. The poultry regulations also permit the use of skin in natural proportions in poultry burgers and patties; hamburger must be made of beef of skeletal origin. Traditional poultry industry practice is the primary basis for these differences.

Page No.	Meat CFR	Poultry CFR
M-3	§ 319.15(b)	§ 381.160
M-46	none	§ 381.168

10. Chilling and Freezing Requirements

The poultry regulations contain numerous requirements concerning time/temperature relationships for the chilling or freezing of poultry carcasses and parts. These requirements consume inspector time to assure compliance. There are no such requirements for meat carcass chilling or freezing. The basis for these differences is traditional industry practice.

Page No.	Meat CFR	Poultry CFR
F-6 to F-10	none	§ 381.66(b)-(c)(5)
F-17 to F-18	none	§ 381.66(e)-(f)(6)

11. Standards of Identity

In similar meat and poultry products with standards of identity, the required percentage content of cooked poultry is usually less than the meat content. For example, "(meat) hash" must contain a minimum of 35 percent fresh meat; "(poultry) hash" must contain a minimum of 30 percent cooked, deboned meat. The basis for these differences is traditional industry practices.

Page No.	Meat CFR	Poultry CFR
M-4	§ 319.300	§ 381.167
M-5	§ 319.301	§ 381.167
	§ 319.302	§ 381.167
	§ 319.304	§ 381.167
M-6	§ 319.305	§ 381.167
	§ 319.311	§ 381.167
	§ 319.312	§ 381.167
M-7	§ 319.313	§ 381.167

12. Moisture Limitations in Processed Products

Moisture limitations in processed products tend to favor poultry. For example:

a) Fresh Meat Sausage must have ≤ 3 percent added water; Fresh Poultry Sausage has no limit.

b) Cooked Meat Sausage must have ≤ 40 percent combined fat and water; Cooked Poultry Sausage has no limit.

c) Pork Ham is protein fat free (PFF) controlled for both Domestic and Foreign Imports; Turkey Ham has no PFF control.

d) Meat Roast must have label declaration of any added moisture; Poultry Roast may contain ≤ 10 percent added moisture without label declaration.

The Appendix's entry under "basis for no comparable [poultry] regulation," with regards to items (a)-(c), is "unknown." With regards to item (d), the "basis for the difference" is traditional industry practices.

Page No.	Meat CFR	Poultry CFR
M-21	§ 319.140	none
M-26	§ 319.180	none
M-14 to M-15	§ 319.104	none
M-16 to M-18	§ 319.105	none
L-76 to L-83	§ 318.19(a)(5)	none
P-39 to P-44	§ 327.23	none

METHOD OF EVALUATION

Figure 1 is a Flow Diagram of the method of evaluation.

Identify Regulatory Requirements for Meat and Poultry

RTI reviewed Title 9, CFR, Subchapters A (Mandatory Meat Inspection, Parts [301-335]) and C (Mandatory Poultry Products Inspection [Part 381])[3] to identify all substantive requirements for meat and poultry, respectively. The substantive regulatory requirements reviewed correspond to 18 specific subject areas, as listed in the Appendix table of contents. All of Title 9, CFR, Subchapters A and C, was included in the study except: 9 CFR § 301.1-2, § 302.1-3, § 303.2, § 318.21, § 318.300-311, § 321.1-2, § 331.1-6, § 381.1-7, § 381.153, § 381.185-186, § 381.220-225, and § 381.300-311. These sections were not included in the comparison because the regulations for meat and poultry were essentially identical in composition or the sections were not considered substantive regulatory requirements for comparison purposes (i.e., they were not included among the required subject categories listed in the Appendix table of contents). RTI used FSIS's Document Issuance Automated Library System (DIALS) to retrieve and download the most current issuance of the CFR.

Division of Comparable and Non-Comparable Meat and Poultry Regulatory Requirements (Part I vs. Part II)

After identifying all substantive meat and poultry regulatory requirements, the RTI staff input regulations into tables using word processing software. The tables were organized by subject category (e.g., "Exemptions") and visually reviewed for comparability. The meat regulations were left essentially intact, and poultry regulations were electronically matched with the appropriate meat regulation. Any meat or poultry requirement not having a similar counterpart requirement was therefore also identified. Accordingly, the regulatory requirements in each subject category are separated into two parts (e.g., the subject category "Exemptions" is broken into "Exemptions [Part I]" and "Exemptions [Part II]"). Part I contains the meat and poultry requirements with comparable counterparts, and Part II contains the meat and poultry requirements without comparable counterparts.

[3]Revised as of January 1, 1992, with ancillaries.

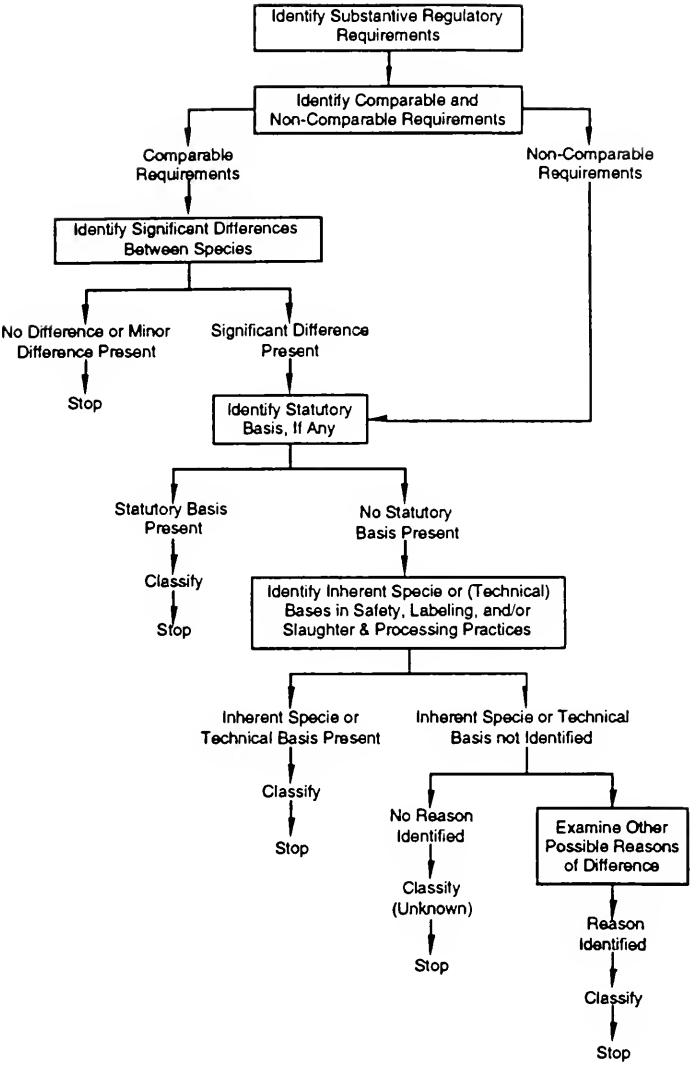

Figure 1. Method of Evaluation

Identify and Classify Differences of Comparable Meat and Poultry Regulatory Requirements (Part I)

Comparable meat and poultry requirements in each category were then reviewed and their differences identified. If there were no differences (i.e., the regulatory requirements were identical), the meat and poultry counterparts were identified as "same" and no further consideration was given. If differences existed, but the burden on the producer for such differences was deemed insignificant, the meat and poultry counterparts were identified as "minor" and no further consideration was given. If differences existed that were deemed significant, then they were summarized and listed in the table.

For the meat and poultry counterparts with significant differences, a classification was then made as to the "basis for differences." Any notes or explanations germane to the differences were also included for informational support. The bases for differences were classified in the following order:

1. *Statutory*

   RTI examined the United States Code (primarily 21 U.S.C. § 451-§ 470 and § 601-§ 695) to determine whether each significant difference identified was based firmly on differences in the statutes. If it was, we noted this fact and gave the U.S. Code citation reference. No further consideration was given to regulatory differences based on statutory differences.

2. *Inherent Specie or Technical Differences*

   Significant regulatory differences between species without a clear basis in statutory differences were further assessed to determine any inherent specie or technical-related basis for the differences. Inherent specie differences (e.g., size, weight, age, type/severity/susceptibility of disease, etc.) or variations in safety, inspection, slaughter, processing, or labeling due to inherent specie differences were the primary bases identified. RTI applied a "general acceptance" rule in making these determinations. If we judged that objective and knowledgeable professionals would generally agree that a regulatory difference can be based on one or more inherent differences in specie-related food safety and/or production methods, we stated so. No further consideration was given to differences of this type.

3. *Other Reasons or Unknown*

   For significant differences without apparent statutory, inherent specie or technical basis, other reasons for the differences were explored. The primary reasons identified were traditional or historical industry practices that were codified into the regulations as the two industries grew and developed. Institutional and operational agency bases for differences were also identified. If no clear basis for a significant difference between meat and poultry regulatory requirements could be identified, then we so noted (e.g., response of "unknown").

Classify the Basis for Non-Comparable Meat and Poultry Regulatory Requirements (Part II)

For non-comparable meat and poultry regulatory requirements, no differences exist to identify or classify. Instead, for these requirements we classified the "basis for no comparable regulation." We followed the same evaluative format as was done for comparable meat and poultry regulatory requirements to determine their "basis for significant differences." In other words, the "basis for no comparable regulation" was identified as (1) Statutory, (2) Inherent Specie or Technical Reason, or (3) Other Reasons or Unknown.

It should be noted that the essential question being answered for non-comparable meat and poultry requirements is much different than the question being answered for those meat and poultry requirements that are comparable . Namely, identifying the "basis for no comparable regulation" (or the reason why there is no meat/poultry counterpart) is not the same as identifying the "basis for differences." There exist no requirements for which to identify differences. Thus the choice of evaluative bases (1), (2) or (3) for non-comparable requirements will not necessarily be the same as when they are being chosen for comparable requirements.

ATTACHMENT C

NEWS

United States Department of Agriculture

Office of the Secretary

Press Secretary Room 201-A Washington, D C 20250

Steve Kinsella (202) 720-4623
Mary Dixon (202) 720-4623

ESPY ANNOUNCES PROPOSAL TO IMPROVE POULTRY INSPECTION SYSTEM

WASHINGTON, March 9 -- Agriculture Secretary Mike Espy today announced USDA will further enhance and strengthen the poultry inspection system to include microbial improvements and the prohibition of all fecal matter on raw product.

"We have made improving the meat and poultry inspection system at USDA a top priority and today's announcement is another move in that direction," said Espy. "We are taking steps to further incorporate science and new technology in the nation's meat and poultry system."

The secretary's Poultry Enhancement Program will be proposed in the Federal Register.

Some of the elements of the program are:

*No amount of fecal matter will be allowed on raw product. When Espy came to office he reinforced this policy for red meat and charged the Food Safety and Inspection Service with drafting a similar proposal for poultry. Fecal matter will no longer be acceptable as part of a finished product standard.

*Regular microbial testing will be mandated on a statistical sampling of product. This will further incorporate science into the system.

*Industry will be required to use FDA-approved rinses that reduce overall bacterial levels on raw product. As more compounds are developed and given FDA approval, immediate use will be allowed.

*The inspection sequence will be changed. Currently, the initial inspection of the poultry carcasses is before the internal organs are removed. Today's proposal calls for the inspection to take place both before and after the internal organs are removed. This will ensure that the carcasses are examined after a key point of potential contamination (organ removal) and before the chiller.

*Fecal-contaminated poultry carcasses will be allowed to be washed inside and outside, rather than trimmed, if the procedure is effective; however, all birds will be re-inspected

-more-

ATTACHMENT C

after reprocessing rather than a sampling. This move is based on a 1993 study which reconfirms the efficacy of washing.

Since coming to office in January, 1993, Espy has made several major improvements to the meat and poultry inspection system, including launching unannounced reviews of plants, hiring additional inspectors, accelerating research on microbial testing and moving toward mandating safe cooking and handling labels for raw meat and poultry.

//

Mr. TOWNS. Thank you. Thank you very much for your statement.

Let me begin by saying, I spend a lot of time trying to phrase questions so they will be sort of yes and no, because I want to be able to cover as much as possible. So the questions that I am going to raise I would like a yes or no answer so we can cover as much as we can.

On July 11, 1988, USDA issued policy memo 022B that said poultry frozen, or previously frozen to 26 degrees or below could not be labeled fresh. Is that correct?

Mr. ROMINGER. Mr. Chairman, I was not here at that time. I believe that was the case. But I believe that policy memo was not implemented, that another memo was issued 6 months later that changed that definition.

Mr. TOWNS. So you are saying yes?

Mr. ROMINGER. Yes, that was issued.

Mr. TOWNS. Thank you. Did any consumer—any consumers or consumer group object to policy memo 022B? Yes or no?

Mr. ROMINGER. I am sorry. Did the consumer groups, did you say?

Mr. TOWNS. Yes. Consumer or consumer groups.

Mr. ROMINGER. I was not here, Mr. Chairman. I don't know who objected if anyone did. All I know is that in reading the record the Department issued another memo 6 months later with different numbers in it.

Mr. TOWNS. So would that be yes or no?

Mr. ROMINGER. I don't know if anyone objected. Or if so, who did.

Mr. TOWNS. Did any State officials object to policy memo 022B?

Mr. ROMINGER. I do not know.

Mr. TOWNS. Does anybody know—let me just ask? This is a hearing, you know, and we are trying to collect some information. And we sent the information to you in terms of the areas of our concern. And you seem to be taking the fifth.

Mr. HORN. Mr. Chairman, could I ask you for a minute?

Mr. TOWNS. I would be delighted to yield to the gentleman.

Mr. HORN. We have got two civil servants, I suspect—maybe I am wrong—on either side. Perhaps they know the answer to your questions.

Mr. TOWNS. Well, I think that we have to ask Mr. Rominger to yield to them and let them answer the questions. So, if for any reason you don't know it—I mean, I think that that would be the normal kind of procedure.

Mr. ROMINGER. I don't believe either of these gentlemen know the answer to that question either.

Mr. TOWNS. What department are you from? I want to make certain we have the right group here.

Mr. ROMINGER. Yes, sir. I am from the Department of Agriculture.

Mr. TOWNS. Oh, OK.

Mr. ROMINGER. I was not here when those policy memos were issued.

Mr. TOWNS. But you did get information indicating the fact that this would be the kind of information we would be seeking?

Mr. ROMINGER. The information I have indicates that after 22B was issued, the Department did have some comments on that regulation, and as a result issued 22C.

Mr. TOWNS. Let me try this then. Did any poultry industry officials object to policy memo 022B?

Mr. ROMINGER. I don't know. I didn't get that information.

Mr. TOWNS. After policy memo 022B was issued, did the Secretary of Agriculture at the time meet with any consumer or consumer representatives on the issue of fresh poultry? A yes or no.

Mr. ROMINGER. I don't know. I wasn't here. I don't know what that Secretary of Agriculture did.

Mr. TOWNS. You know, I am having some problems with this. The fact that you have had all this information, recognizing the fact that these were issues, and you have two staff members with you, and if you weren't there, the question is, were they there? And if not, maybe I should just pass on and let someone else ask a question because we are not going anyplace with this.

Mr. ROMINGER. Mr. Chairman, Mr. Medley would like to answer.

Mr. MEDLEY. Thank you, Mr. Chairman.

Mr. Chairman, we did receive the questions from the subcommittee and we did provide all of the information to our knowledge on the issues presented. The specific questions you are asking now call for conclusions about facts which we don't have. We don't have personal knowledge.

We have provided all documents on all questions forwarded to the Department that we have information within our possession.

We were not personally involved in these programs at the time, in 1988.

Mr. TOWNS. Well, let me ask this question then. If you can't answer this one, I am ready to move on.

According to a draft, internal USDA analysis, dated March 11, 1994, that is current. Although this temperature range was based on the scientific definition of fresh versus frozen poultry, it was not finalized due to pressure from some members of the industry.

Mr. Rominger, did USDA issue policy memo 022C because of pressure from some segments of the poultry industry? Yes or no.

Mr. ROMINGER. I would like Mr. Golden to answer.

Mr. TOWNS. Fine.

Mr. GOLDEN. I don't have any personal knowledge of that, Mr. Chairman, but I do know that the more extensive written testimony provided by the Department points out that 6 months later, on January 11, 1989, after receiving comments from some members of the poultry industry FSIS issued policy memo 22C.

Mr. TOWNS. In January of this year, the Deputy Administrator of your regulatory programs wrote, "Many of the staff feel that the USDA position has not been and is not now reasonable, and that a higher temperature for fresh products is more in line with consumer expectation and yet will not create microbial problems."

Ms. Pat Jensen, the Acting Assistant Secretary for Marketing and Inspection wrote, "This policy has been in existence for many years. It has been embarrassing to the Department on a number of occasions."

Mr. Rominger, why hasn't the Department changed its policy if its own senior staff believe that this is unreasonable and embarrassing.

Mr. ROMINGER. Mr. Chairman, we are in the throes right now of reviewing that policy and would anticipate that if the results of the hearings that we have scheduled and the scientific review that we are doing suggest that the policy should be changed, then that will take place.

Mr. TOWNS. Let me ask unanimous consent that the documents to which I referred be included in the record.

[The information referred to follows:]

United States Department of Agriculture

Food Safety and Inspection Service

JUL 11 1988

To: Branch Chiefs, SLD

Policy Memo 022B

From: Ashland L. Clemons
Acting Director
Standards and Labeling Division, TS

Subject: Use of the Term "Fresh" on Meat and Poultry Products

ISSUE: Under what conditions may the term "fresh" be used on approved labeling of meat and poultry products?

POLICY: This policy memo supersedes Policy Memo 022A. The word "fresh" may not be used in conjunction with the product name of:

1. Any cured product, e.g., corned beef, smoked cured turkey, and prosciutto.

2. Any canned, hermetically sealed shelf stable, dried, or chemically preserved product.

3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core location).

Generally, trademarks, company names, fanciful names, etc., containing the word "fresh" are acceptable, even on products produced in a manner described in 1, 2, or 3 above, provided the term is used in such a manner that it remains clear to the purchaser that the product is not fresh.

Further processed meat and poultry products, such as nuggets, dinners, etc., sold in the refrigerated state, may be labeled as "fresh" even when made from components processed in a manner described in 1, 2, or 3 above.

Labeling not in compliance with the provisions of this policy memo should be modified as soon as possible, but no later than 6 months from the date of this memo.

RATIONALE: This policy memo is issued for the purpose of defining and further clarifying the use of the term "fresh" on approved labeling of meat and poultry products. Historically, from a regulatory point of view, the term "fresh" has been used to describe red meats that have not been cured and raw poultry carcasses and parts that have not been previously frozen. Other uses of the

term have never been clearly defined. This policy memo is an attempt to merge the traditional definition of "fresh" with new consumer perceptions that have developed because of the emergence of new products and the innovative technologies designed to produce and market these products.

In an effort to standardize the requirements for red meat and poultry products, we will no longer allow poultry products which are cured to include the term "fresh" in conjunction with the product name. The regulations (9 CFR 317.8 (b) (6)) presently do not allow cured red meat products to be labeled as "fresh," and we do not believe that there is a valid reason to differentiate cured red meats from cured poultry products. The absence of a similar provision in the poultry regulations is apparently due to the fact that such poultry products were not available at the time the regulations were written.

Products which are canned, hermetically sealed and shelf stable, dried, or chemically preserved, cannot be labeled to include "fresh" in conjunction with the product name since such a use would be inappropriate and misleading.

"Fresh" will continue to be restricted from use in conjunction with the product name on frozen or previously frozen unprocessed poultry. Unlike red meat products, the term "fresh" on poultry, poultry parts, and other edible portions, has acquired marketing significance and offers a meaningful distinction to purchasers between frozen and never frozen products.

"Fresh" may be used on processed products containing ingredients that could not be labeled "fresh" since the term has acquired acceptance when used to identify products sold in the refrigerated state. An example would be a pepperoni pizza or ham salad sold in the refrigerated section of a market. Other products that fall into this category are those in hermetically sealed packages, e.g., vacuum packed meat, which are designed to assure freshness but are not shelf stable and are sold in the refrigerated state. We also recognize that, in many instances, the word "fresh" could be incorporated into the firm name or brand name and used on cured, preserved, and frozen or previously frozen poultry products where it would be highly unlikely that the consumer would be led to believe that he or she was purchasing a fresh product.

P.2

OCT 12 1988

Margaret O'K. Glavin
Acting Assistant Deputy Administrator
Technical Services

Ashland L. Clemons, Acting Director
Standards and Labeling Division
Technical Services

xc Policy Memo on "Fresh" Labeling

The issue of frozen vs. nonfrozen (fresh) poultry was re-visited as a result of a request by Perdue Foods that sought a review of USDA's position on the use of frozen poultry in further processed fresh poultry products.

In a February 26, 1988, letter to Margaret O'K. Glavin, Perdue Foods stated that local inspection personnel would not permit the use of frozen poultry meat in their further processed poultry products. As such, the company asserted that this restriction adversely influenced their production capabilities to the extent of intolerable raw material waste.

The establishment of concern (P-369) specializes in the production of further processed poultry that is customarily sold in refrigerated cases at the retail level that are held at 32 to 40 °F. Labels for these products bear the term "Fresh." The company requested continuation of their method of marketing and labeling these products. Policy Memo 022B provided for reasonable accommodation in this respect.

Nonetheless, the Policy Memo went further in defining the other conditions under which the term "fresh" may be used on the labeling of meat and poultry products. At the request of the Regional Operations staff, we also established a temperature of 26 °F, at which poultry subjected to lower temperatures could not bear labeling indicating that the product was "fresh."

We relied principally on the temperature certification criteria set forth in the "Poultry Graders Handbook" for this purpose (applicable pages enclosed). We also attempted to secure baseline temperature data from various universities, including: Maryland, Cornell, Georgia, Arkansas, Mississippi State, Texas A&M, Ohio State, Iowa State, Alcorn State, and others, but were not entirely successful in obtaining sufficient temperature data upon which to base an objective decision. Nearly all of these institutions stated that a temperature of 32 °F was acceptable to support the labeling of "fresh" poultry products. It was noted by each that there is a difference between refrigeration and cool storage on the one hand and freezing and frozen storage on the other. Further distinctions between refrigeration and freezing temperatures are indeed related to micro-organism activity, as the National Broiler Council has

asserted. However, the issue of concern is not with frozen product labeling or with the obvious protection from microbial spoilage that freezing provides; rather, it is a matter related solely to various perceptions of what is "fresh" and the associated labeling of products which bear this term.

While pure water will freeze at 32 °F, most foods, including poultry, will not begin to freeze until about 28 °F or lower is reached. The freezing point of red meat foods is typical of the latter temperature, and the average freezing point of fresh poultry is 27 °F (Food Science, Fourth Edition, Porter). Therefore, the 26 °F temperature appears to be very soundly based and is, in fact, another very generous accommodation towards the industries needs, both from a safety and esthetics perspective. As you know, we are preparing a revision to Policy Memo 022B which will allow unfrozen raw poultry covered by item 3. to be labeled as "fresh," provided the internal temperature falls within the range of 28 to 24 °F. The optimal target temperature of 26 °F will not change, and processors are encouraged to aim for this target. This range of 28 to 24 °F will compensate for any variability inherent or indicative of existing cooling practices employed within official plants.

Enclosure

United States Department of Agriculture

Food Safety and Inspection Service

JAN 11 1989

To: Brancn Chiefs, SLD

Policy Memo 022C

From: Ashland L. Clemons, Acting Director
Standards and Labeling Division
Technical Services

Subject: Use of the Term "Fresh" on Meat and Poultry Products

ISSUE: Under what conditions may the term "fresh" be used on approved labeling of meat and poultry products?

POLICY: This policy memo supersedes Policy Memo 022B. The word "fresh" may not be used in conjunction with the product name of:

1. Any cured product, e.g., corned beef, smoked cured turkey, and prosciutto.

2. Any canned, hermetically sealed shelf stable, dried, or chemically preserved product.

3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit.

Generally, trademarks, company names, fanciful names, etc., containing the word "fresh" are acceptable, even on products produced in a manner described in 1, 2, or 3 above, provided the term is used in such a manner that it remains clear to the purchaser that the product is not fresh.

Further processed meat and poultry products, such as nuggets, dinners, etc., sold in the refrigerated state, may be labeled as "fresh" even when made from components processed in a manner described in 1, 2, or 3 above.

Since there are no anticipated labeling changes necessary as a result of the modifications made in this policy memo, the January 11, 1989, date set in Policy Memo 022B for compliance with these provisions is still in effect.

RATIONALE: This policy memo is issued for the purpose of defining and further clarifying the use of the term "fresh" on approved labeling of meat and poultry products. Historically, from a regulatory point of view, the term "fresh" has been used to describe red meats that have not been cured and raw poultry carcasses and parts that have not been previously frozen.

FSIS 2630-6(12/79)

Other uses of the term have never been clearly defined. This policy memo is an attempt to merge the traditional definition of "fresh" with new consumer perceptions that have developed because of the emergence of new products and the innovative technologies designed to produce and market these products.

In an effort to standardize the requirements for red meat and poultry products, we will no longer allow poultry products which are cured to include the term "fresh" in conjunction with the product name. The regulations (9 CFR 317.8(b)(6)) presently do not allow cured red meat products to be labeled as "fresh," and we do not believe that there is a valid reason to differentiate cured red meats from cured poultry products. The absence of a similar provision in the poultry regulations is apparently due to the fact that such poultry products were not available at the time the regulations were written.

Products which are canned, hermetically sealed and shelf stable, dried, or chemically preserved cannot be labeled to include "fresh" in conjunction with the product name since such a use would be inappropriate and misleading.

Policy Memo 022B is being revised to reflect the deletion of the provision that established 26 degrees Fahrenheit (or less) as the threshold temperature at which unprocessed poultry products could not be labeled as "fresh." The Agency has now decided, after much deliberation on this issue, not to limit the use of the term "fresh" on unprocessed poultry products based on an internal temperature with the exception as defined by the current regulations, i.e., product is above zero degrees and below 40 degrees Fahrenheit, and has not been previously frozen at or below zero degrees Fahrenheit. This decision is predicated on the belief that it is not practical under existing marketing strategies and distribution patterns, to define "fresh" in terms of internal temperature beyond the scope of the current regulations, nor is it practical to define consumer expectations for poultry products labeled as "fresh." The consumer is the best judge of preference in chilling temperatures for unprocessed poultry products labeled as "fresh," and therefore the marketplace is best suited for making this type of decision.

"Fresh" may be used on processed products containing ingredients that could not be labeled "fresh" since the term has acquired acceptance when used to identify products sold in the refrigerated state. An example would be a pepperoni pizza or ham salad sold in the refrigerated section of a market. Other products that fall into this category are those in sealed packages or containers, (e.g., vacuum packed meat and the newer thermoformed oxygen barrier multilayer films), which are designed to assure freshness but are not shelf stable and are sold in the refrigerated state. We also recognize that, in many instances, the word "fresh" could be incorporated into the firm name or brand name and used on cured, preserved, and frozen or previously frozen poultry products where it would be highly unlikely that the consumer would be led to believe that he or she was purchasing a fresh product.

JAN 07 1994

TO: H. Russell Cross
Administrator

FROM: John W. McCutcheon, Deputy Administrator
Regulatory Programs

SUBJECT: California "Fresh" Law

California passed a law that will require poultry products chilled to less than 26 degrees to be labeled "fresh." USDA permits the term "fresh" to be used down to zero degrees. Due to Federal preemption, a court case was brought by the National Broiler Council, (NBC) to stop the State from implementing this law on January 1, 1994. We received a very strong opinion by the court on the Federal preemption issue when it granted the injunction. It is likely that the California law will not ever be effective. However, at least one other state has a law on its books that conflicts with USDA policy.

Many on the staff feel that the USDA position has not been and is not now reasonable and that a higher temperature for "fresh" products is more in line with consumer expectations and yet will not create microbial problems. We tried a number of years back to come up with a new temperature, but were stopped by the lack of agreement on a reasonable figure.

Years ago, I was able to resolve a long standing issue among the states, USDA, and the industry, by agreeing to the National Institutes of Science and Technology, (NIST) formally the National Bureau of Sciences, (NBS) organizing a task force under the auspices of the National Conference of Weights and Measures. The issue resolved was the long standing net weight issue that also started in California with the Rath Bacon case. I have talked with NIST and they will be willing to do the same thing to get agreement on the definition of "fresh" if USDA is interested.

I support trying to get agreement among the states, industry, and ourselves on the issue of "fresh." I also support having this group take the lead since we would be responding to their request and we would not have to take the heat on opening the issue. Once all the parties agree on the approach, then we can follow with regulations that will be non controversial since all parties will have already had their input. In the earlier group we had FDA, NBC, NTF, AMI, a consumer representative, and all the states. The same make up should be proposed for this group. Informally, I have asked NBC and NTF to get me a reaction to the proposal.

Please let me know your reaction to this. I can either encourage the NIST group to formally ask for a task force or not.

JAN 19 1994

INFORMATIONAL MEMORANDUM FOR THE DEPUTY SECRETARY

FROM: Patricia Jensen
Acting Assistant Secretary
Marketing and Inspection Services

SUBJECT: The Department's Position on the Definition of "Fresh" Poultry

ISSUE:

Is this a good time for USDA to reconsider its policy on the definition of "fresh" poultry?

DISCUSSION:

The Food Safety and Inspection Service, (FSIS) in its responsibility for managing meat and poultry inspection, has a policy that a raw poultry product cannot claim on its label that it is fresh if it has been previously frozen. The meat and poultry regulations define "frozen" as zero degrees or lower. Consequently, any raw poultry product that is just above zero degrees can be called "fresh" on the package, e.g., fresh chicken, fresh turkey, fresh chicken breasts, etc.

This policy has been in existence for many years and has been embarrassing to the Department on a number of occasions. For example, Frank Purdue ran a series of TV advertisements that showed his pliable chickens and he then drove a nail into a board with a competitor's chicken. Both products were correctly labeled "fresh" with USDA approved labels. Frank Purdue then, in the ad, commented on the insensibility of the Government's policy. FSIS tried to change the policy about five years ago, but was unsuccessful in getting agreement on a new temperature for a lower limit for "fresh" poultry.

The issue resurfaced again when California passed a law that prohibits wholesalers from labeling or marketing as "fresh" any poultry product which (a) has ever reached an internal temperature at or below 25 degrees F or (b) has been stored for 24 hours or more at average ambient temperatures at or below 25 degrees F. The law was to be effective January 1, 1994. The National Broiler Council, American Meat Institute, and the Arkansas Poultry Federation filed a lawsuit to stop the State

from enforcing the law. On December 22, 1993, the Judge enjoined enforcement of the part of the law regarding labeling. Subsequently, the Judge requested that USDA explain its position as "a friend of the court."

Since Federal preemption is key to the Department's statutory authority in the area of meat and poultry inspection, USDA has requested that the Department of Justice, (DOJ) file a brief on USDA's behalf, positing that the California law is preempted. However, to do so, without revisiting the policy, potentially puts USDA in the position of being anti-consumer. We very likely will be able to win the case on the issue that a state cannot adopt rules that are in addition to or different than Federal rules, but reasonableness of the Federal policy position will be questioned during the process. In fact, when the California law was being debated, the supporters of the law used a Federal "fresh" chicken as a bowling ball in front of the State Capitol.

On Wednesday, January 26, 1994, counsel for the California Poultry Industry Federation, (CPIF) met with Acting Assistant Secretary Pat Jensen, staff from OGC and FSIS, and a representative of DOJ. It was clear they are serious about seeing that the California law is implemented and fully intend to seek to embarrass the Department on its policy position. We can expect numerous Congressional contacts on this issue to be initiated with officials throughout the Department.

If the Department decides to reconsider its "fresh" policy, we may want to seize the initiative by announcing or issuing an advanced notice of proposed rulemaking as a vehicle for such policy reappraisal. By publicly seeking views on how best to regulate "fresh" poultry claims, we could offset any adverse inferences the CPIF might seek to draw from our defense of Federal preemption of the state statute. The Department might then be perceived as initiating a consumer protection policy on this issue, rather than be seen as merely reacting defensively to a California poultry proposal for a new policy.

03/28/94 08:09 ☎202 205 7814 USDA/FSIS

FAX TRANSMITTAL

To Jerry Caroselle	From Jim Rasell
Dept./Agency FSIS/Marshall's	Phone # 202-254-2529
Fax # 720-4662	Fax # 202-254-2499

GENERAL SERVICES ADMINISTRATION

3/11/94

DRAFT

Analysis of the Issues on "Fresh VS Frozen" on Poultry

Issues:

0 - On September 27, 1993, the state of California enacted a state law restricting the use of the term "fresh" to describe poultry products that has never been at or below 25 degrees Fahrenheit (Section 26661 of the California Food and Agriculture Code). Section 26661 was scheduled to take affect on January 1, 1994.

Are you talking about poultry products or eggs?

0 - The current USDA Policy Memo 022C states that the word "fresh" may not be used in conjunction with the name of any poultry that has been frozen or previously frozen at or below Zero degrees Fahrenheit.

0 - On December 2, 1993, The National Broiler Council (NBC), American Meat Institute (AMI), and the Arkansas Poultry Federation (APF), brought suit seeking to have California permanently enjoined from enforcing section 26661. Plaintiffs argue that Section 26661 of California Law is explicitly preempted by the Poultry Products Inspection Act (PPIA) because it imposes labeling requirements which are in addition to, or different than, those required by the PPIA.

DRAFT

dried, or chemically preserved products. The Policy Memo 022B further stated that any poultry, poultry part or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core) can not bear the term "fresh" (PAD File).

On December 8, 1988, The Policy Memo 022B was modified to Policy Memo 022C. The Policy 022C stated that "Fresh" will continue to be restricted from use in conjunction with the product name on frozen or previously frozen unprocessed poultry. Unlike red meat products, the term "fresh" on poultry has acquired marketing significance and offers a meaningful distinction to ?consumers? purchasers between frozen and never been frozen products. The policy further stated that Policy Memo 002C is being issued to allow for unprocessed poultry products to be labeled "fresh" provided that the internal temperature falls within the range of 28 degrees fahrenheit to 24 degrees Fahrenheit at its core. This change was made due to the inherent variability in the processing, handling and transportation of poultry products. (PAD File) Although, this Policy Memo 022C was based on scientific definition of "fresh" vs "frozen" poultry ~~but because of~~ due to pressure from some members of industry it was not finalised. The Agency file on "fresh" vs "frozen" indicated that NBC requested that the temperature break point of "fresh" vs "frozen" be set at 20 Fahrenheit. On the other hand some members of industry asked ~~The~~ Agriculture Secretary Richard Lyng to implement a policy

4

9 JAN 1991

Ms. Rosemary Mucklow
Western States Meat Association
P.O. Box 12944
Oakland, CA 94604-9895

Dear Ms. Mucklow:

This is in response to your December 17, 1990, letter regarding the use of the term "fresh" on poultry products chilled to one degree Fahrenheit.

As you are aware, prior to the publication of Policy Memo 022C on January 11, 1989, we published Policy Memo 022B which limited the use of the term "fresh" to poultry products that had not been frozen to 26 degrees Fahrenheit or below (at its center or core location). Shortly after the publication of Policy Memo 022B, much pressure was placed on the Department to rescind the policy since it created a new category of poultry products that was beyond the purview of the regulations. After a great deal of deliberation on this issue, the Agency decided not to limit the use of the term "fresh" on poultry products based on an internal temperature except as limited by the current regulations in 9 CFR 381.66, i.e., product may be labeled as "fresh" if it exists above zero degree and below 40 degrees Fahrenheit and has not been previously frozen at or below zero degree Fahrenheit.

The decision to maintain what essentially results in the status quo was difficult and controversial. Since Policy Memo 022B would have dramatically changed traditional and longstanding practice of the poultry industry and since opposing views were so passionately expressed, the issue upon appeal reached the Secretary's office. There it was decided that the marketplace was best suited to decide if any future changes were necessary.

Unlike poultry products, the term "fresh" used on red meat products has only been associated with uncured products. This is captured in the regulation 9 CFR 317.8(b)(6). Thus, frozen red meat, e.g., ground beef, may be labeled "fresh."

If you have any further questions, please do not hesitate to contact us.

Sincerely,

Ashland L. Clemons, Director
Standards and Labeling Division
Regulatory Programs

FSIS:RP:SLD:LPAB:JONES:75388:01-02-91
Sally's Disc #3 File Name: Fresh
Subject: Fresh on poultry products

Clearance	Initials	Date
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Federation

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

NATIONAL BROILER COUNCIL, and AMERICAN MEAT INSTITUTE, and ARKANSAS POULTRY FEDERATION, INC., Plaintiffs, vs. HENRY J. VOSS, Director, California Department of Food and Agriculture, Defendant.	CASE NO. CV-S- 93-1882 DFL JFM DECLARATION OF DR. LESTER CRAWFORD IN SUPPORT OF JOINT MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON COUNT 1

DECLARATION OF DR. LESTER CRAWFORD

I, Dr. Lester Crawford, declare as follows:

1. I am the Executive Director of the Association of American Veterinary Medical Colleges in Washington, D.C. I have personal knowledge of all of the facts stated in this declaration and, if called as a witness, could and would testify thereto under oath.

2. I received a Doctorate in Veterinary Medicine from Auburn University in 1963. I received a Doctorate in Pharmacology from the University of Georgia in 1969.

3. I was a Professor of Veterinary Medicine at the University of Georgia from 1966 to 1978 and from 1980 to 1982. At the University of Georgia, I headed up the Department of Physiology and Pharmacology.

4. I was the Director of the Center for Veterinary Medicine in the United States Food and Drug Administration ("FDA") from 1978 to 1980 and from 1982 to 1985. As Director of the Center for Veterinary Medicine in the FDA, I was the final authority with respect to veterinary drug approvals, animal feed regulation, animal device regulation, and animal drug regulation.

5. I was the Associate Administrator of the Food Safety and Inspection Service ("FSIS") of the United States Department of Agriculture ("USDA") from December, 1985 to September, 1987. I was the Administrator of the FSIS from October, 1987 to September, 1991. As Administrator of the FSIS, I was the highest official at the FSIS.

6. As Administrator of the FSIS, I reported to the Secretary of Agriculture. I was the final authority at the FSIS on all matters pertaining to federal inspection and labeling of meat and poultry. In my capacity as Administrator, I was responsible for approving or disapproving all plants that were eligible for production of both raw and processed meat and poultry, and products containing meat or poultry. Furthermore, I was responsible for the correct labeling of all meat, poultry, and products containing meat or poultry sold in the United States.

7. As Administrator of the FSIS, I oversaw the issuance of and reviewed all policy memos from October, 1987 to September, 1991. Under my administration, policy memos were used sparingly since they were designed only to reflect the developing thinking of the FSIS. Policy memos are not intended to state the permanent position of the FSIS. Rather, policy memos are meant to set out the current FSIS position.

8. In contrast, when the position of the FSIS is finalized, the position is stated in a regulation. The position of the FSIS is not legally enforceable until it becomes a regulation. Thus, if a party refuses to comply with a policy memo, the FSIS would have to relent because a policy memo is not legally enforceable. When the FSIS is ready to enforce a position in court, the FSIS states the position in a regulation.

9. Very few policy memos have resulted in the issuance of formal regulations. Indeed, when policy memos are challenged, they are often withdrawn or modified to meet the needs of the opposition.

10. Since policy memos are not final agency determinations nor do they have the force of law, policy memos are not intended to be preemptive of state law or any other law, or to be regulations or legal requirements. They are merely intended to give interested parties some insight into the current thinking of the FSIS. Policy memos are also considered to be useful in instructing those industries which are regulated and inspected by the FSIS.

11. During my tenure as Administrator, the FSIS issued two policy memos regarding the issue of labeling meat and poultry products as fresh. Policy Memo 022B, which is attached as Exhibit 1, was issued on July 11, 1988. Policy Memo 022C, which is attached as Exhibit 2, was issued on January 11, 1989.

12. In 1988, Perdue Farms, a major poultry producer, requested the FSIS to investigate the labeling of poultry as fresh. During our investigation, we found that a great deal of the poultry products that were labeled as fresh were clearly frozen. We believed that it was misleading and unfair to the consumer to label poultry as fresh when it was clearly frozen. Thus, we set out to develop a policy memo aimed at more accurate, informative, and fair labeling of meat and poultry products as fresh.

13. As a result of scientific research regarding the freezing of poultry, including a survey of the relevant scientific literature and studies conducted in FSIS laboratories, we concluded that 26 degrees Fahrenheit was the best dividing line between fresh and frozen poultry. This conclusion was based on our finding that ice crystal formation is present in the edible portions of the poultry carcass at and below 26 degrees Fahrenheit.

14. We memorialized our thinking on this issue in Policy Memo 022B. In Policy Memo 022B, the FSIS stated that "[a]ny poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core location)" could not be labeled as fresh. Exhibit 1, page 1, paragraph #3.

15. After the issuance of Policy Memo 022B, representatives of the poultry industry approached the Secretary of Agriculture Richard Lyng and me. Secretary Lyng and I had two meetings with certain members of the National Broiler Council ("NBC"), including Holly Farms and Marshall Durbin, who differed with the conclusions stated in Policy Memo 022B.

16. Secretary Lyng instructed me to meet with the members of the NBC to resolve the issue. Secretary Lyng told me to work with the NBC members and to develop an acceptable accomodation.

17. I met with certain members of the NBC. I was told that the vast majority of the NBC members wanted Policy Memo

022B abrogated. The NBC was unwilling to accept any compromise position. The NBC's position was that Policy Memo 022B be rescinded.

18. During the consideration of Policy Memos 022B and 022C, no consumers or state officials had input into these policy discussions.

19. Given the position of the NBC, I reluctantly rescinded Policy Memo 022B. On January 11, 1989, the FSIS issued Policy Memo 022C, which superseded Policy Memo 022B. In Policy Memo 022C, we stated that "[a]ny poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit" could not be labeled as fresh. Exhibit 2, page 1, paragraph #3.

20. I still believe that the conclusions stated in Policy Memo 022B were and are correct. I also continue to believe that it is misleading to label poultry that has been frozen to 26 degrees Fahrenheit or below as fresh because such poultry is clearly frozen. The change from 26 to zero degrees Fahrenheit was made as a political compromise.

21. Neither 022B nor 022C were intended to be preemptive of state law or any other law, or to be regulations or legal requirements. They were merely intended to set out the current thinking of the FSIS regarding the issue of labeling meat and poultry products as fresh.

22. Neither the USDA nor the FSIS has any current requirements mandating the labeling of poultry as fresh.

23. There are no laws or regulations on the books defining fresh poultry. The USDA has intentionally left a regulatory void in this area. Thus, the USDA has left it up to the states to define fresh poultry.

24. I have reviewed the California fresh poultry consumer protection law being challenged in this case, and believe it is a valid and worthwhile attempt to bring greater consumer protection into this area. I do not believe that the California law is preempted by any federal labeling requirement of the USDA that I am aware of.

25. I do not concur in the position that the USDA or the FSIS has total control over marketing and labeling of poultry, nor that the states are precluded from passing any laws regarding poultry labeling unless they are identical to federal regulations. I believe that the states are entitled to protect their consumers from misleading marketing and labeling of poultry when the USDA has not acted in the area.

26. I do not believe that the California law requires the addition of anything to poultry labeling. Nor do I believe that there is any current federal requirement that requires the affirmative labeling of poultry as fresh.

Executed this 24th day of February, 1994 at Washington, D.C.

I declare under penalty of perjury that the foregoing is true and correct.

Dr. Lester Crawford

PROOF OF SERVICE

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action. My business address is 1800 Avenue of the Stars, Suite 900, Los Angeles, California 90067.

On March 11, 1994, I served the foregoing document described as **DECLARATION OF DR. LESTER CRAWFORD IN SUPPORT OF JOINT MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON COUNT 1** on all interested parties in this action as stated on the attached service list.

__X__ (BY EXPRESS MAIL) I placed true copies of the foregoing document in sealed envelopes addressed as stated on the attached service list. I caused each such envelope, with postage thereon fully prepaid, to be deposited with the United States Postal Service. I am readily familiar with Irell & Manella's practice for collection and processing of correspondence for mailing with the United States Postal Service. Under that practice, the correspondence would be deposited with the United States Postal Service on that same day with postage thereon fully prepaid at Los Angeles, California in the ordinary course of business.

Executed on March 11, 1994, at Los Angeles, California.

I certify that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

I declare under penalty of perjury that the foregoing is true and correct.

Larry M. Polon
Name

Signature

SERVICE LIST

NATIONAL BROILER COUNCIL, et al., v. VOSS

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Mr. TOWNS. And let me just say this before I conclude. I guess you detected I am a little disappointed in some of your answers. But when will this be concluded?

Mr. ROMINGER. When will the analysis be concluded?

Mr. TOWNS. Yes.

Mr. ROMINGER. We will be scheduling hearings and I would expect that sometime later this summer or fall we would have all of the information and be ready to make a decision.

I think the important thing is that this Secretary of Agriculture has said we will review this labeling issue and make the adjustments as necessary.

Mr. TOWNS. Before I yield to Mr. Condit, let me just ask a question, just for information.

Mr. Medley, how long have you been with the Department?

Mr. MEDLEY. I have been with the Department of Agriculture 17 years. I have been at FSIS since February of this year.

Mr. TOWNS. Not new.

Mr. Golden.

Mr. GOLDEN. I have been with the Department of Agriculture for 11 years, and I have been with the Federal Government for over 20 years.

Mr. TOWNS. Mr. Rominger, may I ask a question. When you bring assistants with you, do they have to serve a purpose?

Mr. ROMINGER. Yes. They are here to answer questions that they have knowledge of.

Mr. TOWNS. I yield to Mr. Condit.

Mr. CONDIT. Thank you, Mr. Chairman.

Thank you, Mr. Rominger, for being here today. I have a series of questions to ask, and if you can do yes or no, that would be preferable. If not, and I can't get through them, I would like to submit those to you and you can respond to them in writing.

Is it the USDA's intention to issue a new policy memo or undergo a formal rulemaking as a result of its reevaluation of the fresh labeling?

Mr. ROMINGER. Yes.

Mr. CONDIT. Mr. Clements stated in his October 1988 memo, which I believe you have, that the issue of concern is not the frozen product labeling or with the obvious protection from microbial spoilage. Rather it is a matter related solely to the various perceptions of what is fresh.

Has your policy changed, or do you agree with Mr. Clements?

Mr. ROMINGER. I think we have concerns both for consumer perceptions of what is fresh as well as the food safety issues. We want to examine both of those.

Mr. CONDIT. Ms. Jensen's January 1994 memo on the Department's definition of fresh poultry states that the current policy has been embarrassing to the Department on a number of occasions.

Do you share that view?

Mr. ROMINGER. Yes.

Mr. CONDIT. In a memo from, I guess it is Mr. John Hutchinson—Hutchins, states that many of the staff feel that the USDA's position has not been and is not now reasonable, and changing it will not create microbial problems.

How do you feel about that statement? And you are welcome to go beyond yes and no.

Mr. ROMINGER. Well, as I indicated, we are reviewing the scientific information. What information that I have received at this point indicates that the water in the chicken does begin to freeze when you get down to 28, 26 degrees, but not all of the microbial action stops until you get down to about zero degrees Fahrenheit. So we are examining that entire range to see what would be the best for consumers.

Mr. CONDIT. So you think you are in the process of redefining the issue again?

Mr. ROMINGER. Yes.

Mr. CONDIT. Was Mr. Hutchin's suggestion that a National Institute of Science and Technology task force be formed to gain a consensus on this matter ignored?

Mr. ROMINGER. We do intend to submit this to the National Advisory Committee on Microbiological Criteria.

Mr. Medley would like to answer.

Mr. MEDLEY. I think that that recommendation goes to the need to have independent, outside review of the issue, and with the standing Micro Committee, we felt that would give us that review in the most timely manner.

Mr. CONDIT. So you don't feel it has been ignored. You just delayed your time period or what?

Mr. MEDLEY. No, sir, it has not been ignored. We have decided to utilize an alternative which gives us a more expeditious review of that issue.

Mr. CONDIT. I would like to show you a picture of a Tyson shipping box. You will notice that it states that the freezing point of the poultry is 28 to 32 degrees. This box is addressed to "Mr. Retailer."

Does it bother you that the USDA labels that are supposed to be for the benefit of the consumers lack similar information? And I think you have this photo in front of you.

Mr. ROMINGER. Yes.

Mr. CONDIT. Do you have any comment about that, Mr. Rominger.

Mr. ROMINGER. I am sorry, Mr. Chairman. What is the question?

Mr. CONDIT. Does it bother you that the USDA labels that are supposed to be for the benefit of consumers lack similar information?

Mr. ROMINGER. The USDA, I don't believe, is the one that puts labels on these packages. These are the labels that the processor puts on.

Mr. MEDLEY. Mr. Condit, I would also like to add that this goes to shelf life and stability of the product, and we do have with our safe handling labels information which goes to the proper handling for food safety.

Mr. CONDIT. Well, let me put it this way. The USDA approves the labels.

Mr. ROMINGER. USDA approves labels, yes.

Mr. CONDIT. OK. Does it bother you that they are supposed to benefit the consumer and that we don't have similar information for the consumer on the product?

Mr. ROMINGER. I guess I am not sure of the question. This information, I guess, is available to the consumer, isn't it?

Mr. CONDIT. It is not on the—it is not labeled.

Mr. MEDLEY. The question is why this information is not on the individual package——

Mr. CONDIT. There you go. There you go. Thank you for helping me.

Mr. MEDLEY. All the information that is on the package, we do have to preapprove. As stated in my earlier statement, we do believe that there should be information on the package that addresses food safety and that is why the safe handling labels were mandated and are on the specific packages.

This goes to shelf life. With regard to safety, we do have information on the package. As of July 6, all raw products will have that information.

Mr. CONDIT. It looks to me like the FSIS staff did a pretty thorough job of researching the literature and science on poultry in 1988 to 1989.

Has the science changed that much that you need at least 5 months to review it in 1994?

Mr. MEDLEY. Mr. Condit, there has been some addition. But we are doing beyond just looking at physical characteristics, we are looking at spoilage and bacteria growth. A very difficult question was raised earlier, as to what range or what is the proper temperature, and we are looking at that evaluation to answer the question.

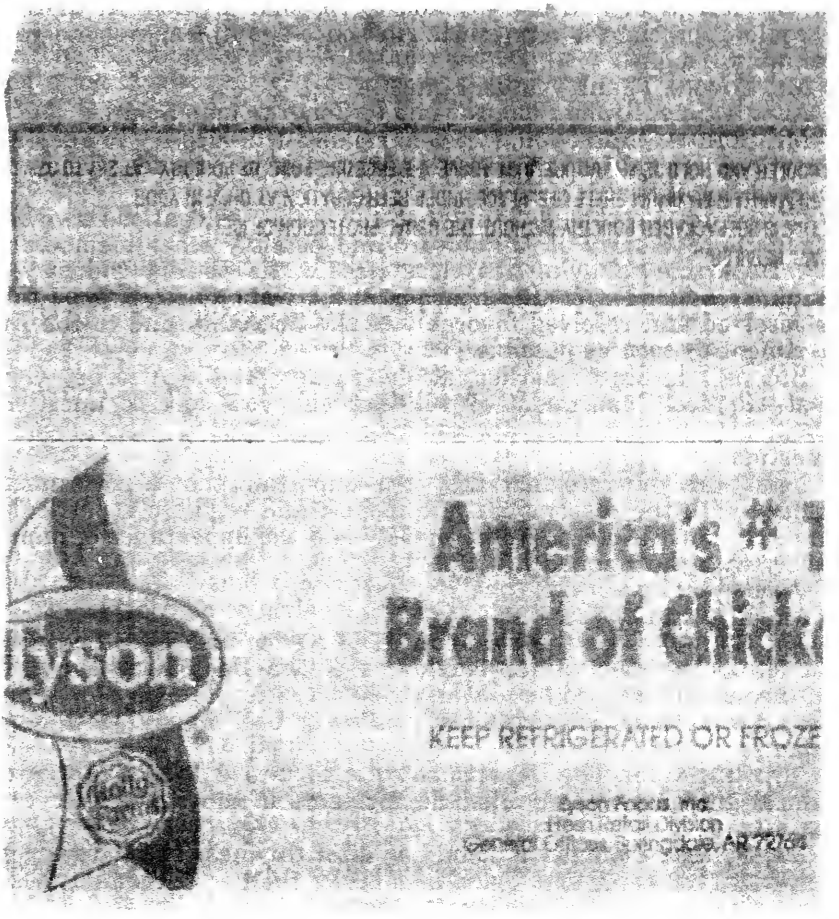
Mr. CONDIT. You know, we have been doing this chicken and turkey thing for a long time, and I don't think the science has changed very much. I mean, I don't understand why there has been such a delay in coming up with a policy that is accurate. I mean, it just is a real surprise to me.

The red light is on for me, and I apologize.

I ask unanimous consent to include the referenced label in the record, Mr. Chairman, if I may?

Mr. TOWNS. Without objection.

[The information referred to follows:]


America's #
Brand of Chick
KEEP REFRIGERATED OR FROZE
AR 72764

Mr. CONDIT. And I have several other questions if I may submit to Mr. Rominger and ask for him to respond to them in writing. I would appreciate it very much. And once again, I appreciate your being here today.

Mr. TOWNS. Thank you very much.

At this time, I would like to yield to Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. I will also try to keep my questions brief, Mr. Rominger. I would ask you to keep your answers brief, if that is possible.

I have to say that I think that the public allegations swirling about the Secretary of Agriculture and possibly other members of the Department having too close ties to the poultry industry, I think, is a cloud over this hearing, and I want to say I hope that is resolved and resolved favorably to the Secretary and to the Department as soon as possible.

But as I indicated earlier, at the request of the Attorney General—Justice Department, I will not ask you specific questions about any of that. But I would like to ask you a general policy question.

I am sure you recognize that it is important that a government agency with the responsibility to inspect and regulate a particular industry must avoid both impropriety and the appearance of impropriety with that industry.

Would you agree with that?

Mr. ROMINGER. Yes.

Mr. SCHIFF. Does the Department of Agriculture have any written ethical guidelines for employees of the Department of Agriculture in this regard as to what they may accept, if anything, and under what condition, from the poultry or beef or any other regulated industry?

Mr. ROMINGER. The Department of Agriculture does have written ethical guidelines as do other departments in the Federal Government.

Mr. SCHIFF. I wonder if sometime after this hearing, at your convenience, you could send each member of the two subcommittees a copy of those ethical guidelines as they relate to this question.

[The information can be found in appendix 7.]

Mr. SCHIFF. Moving now to the specific subject of poultry, it has been suggested that poultry producers are not inspected as often as beef producers by the Department of Agriculture. In your opening statement, you made reference to inspections, unannounced inspections of poultry producers.

Does the Department of Agriculture inspect poultry producers as often, even if it is on a proportional basis, as it inspects beef producers?

Mr. ROMINGER. Yes, I believe we do.

Mr. SCHIFF. It has also been suggested that the standards for inspection for poultry and beef differ. The beef producers maintain they are held to a zero tolerance level for fecal contamination for beef. But this is not correct for possible fecal—not the same for possible fecal contamination of poultry.

Is that suggestion correct? Or is that suggestion not correct?

Mr. ROMINGER. I believe that suggestion is not correct. I would ask Mr. Medley to expand, if you would like.

Mr. SCHIFF. Please.

Mr. MEDLEY. Thank you. The Department has always maintained a policy of prohibiting fecal contamination on meat or poultry. The question here is: Was there a need to reinforce the implementation of that policy? And that has occurred. And the difference is that it occurred in red meat and the process of that reinforcement is now occurring in poultry. There is a difference.

Mr. SCHIFF. What does reinforcement mean, as you use that word here?

Mr. MEDLEY. Reinforcement, Congressman, there are a number of policy goals and objectives that are achieved through regulations that are implemented by our inspection force. Periodically what you need to do is reassure that everyone in the inspection force is uniformly enforcing these regulations.

Mr. SCHIFF. So you mean do closer inspection on the issue?

Mr. MEDLEY. That is part of it, yes, sir.

Mr. SCHIFF. But is the basic standard for fecal contamination, according to U.S. Department of Agriculture, the same for beef as for poultry?

Mr. MEDLEY. No, sir, it is not. Because the finished product standards which get into that are different.

Mr. SCHIFF. Well, now, excuse me. But I thought that is not what you said a minute ago. I thought you said there was no difference.

Mr. MEDLEY. I said that the policy on zero fecal contamination was the same. The objective was the same. Regulations which have been promulgated 50 years apart to implement that are different.

Mr. SCHIFF. Please explain how they are different?

Mr. MEDLEY. The regulations for the poultry, since they were promulgated 50 years later, are more specific. They are more prescriptive. They are more detailed in what the requirements are.

Mr. SCHIFF. For red meat?

Mr. MEDLEY. For poultry. That is why there was a policy for red meat and you were able to then institute zero tolerance by a policy directive.

The RTI study, which we provided to the committee, which went through a side-by-side comparison, pointed out that there were differences. This was one of the areas. With regard to the tolerance, there is a difference in terms of the standards.

Mr. SCHIFF. Well, are you more tolerant in terms of the standards for poultry or more tolerant in terms of the standards for red meat?

Mr. MEDLEY. I would say that at this point in time because of finish product standards for poultry, it would be more tolerant in the poultry area. Yes, sir.

Mr. SCHIFF. Turning to the issue of frozen, it is my understanding that the policy of the U.S. Department of Agriculture is that poultry can be labeled fresh if it is cooled not below zero degrees Fahrenheit. Is that correct?

Mr. MEDLEY. That is correct.

Mr. SCHIFF. Now, at 2 degrees Fahrenheit, poultry is going to be frozen—is going to be hard as a rock, is it not?

Mr. ROMINGER. Yes, it undoubtedly will be.

Mr. SCHIFF. All right. But even though it is hard as a rock, it can still be labeled fresh according to Department of Agriculture?

Mr. ROMINGER. According to the current definitions, that is correct.

Mr. SCHIFF. Is there a similar freezing—fresh freezing issue with respect to red meat or pork or any other meat product?

Mr. ROMINGER. I am not sure whether you would say it is similar, but yes. In red meat, the meat can be labeled fresh as long as it has not been cured, in other words, nitrates or other things used to cure it. So in red meat, the term fresh has nothing to do with temperature. It can be frozen and then thawed out and still labeled as fresh under red meat regulations?

Mr. SCHIFF. So according to Department of Agriculture, red meat can be frozen and unfrozen and labeled fresh. The consumer sees the label fresh?

Mr. ROMINGER. That is correct. The difference has to do with curing rather than the temperature.

Mr. SCHIFF. Do you think most consumers realize that?

Mr. ROMINGER. I am not sure.

Mr. SCHIFF. Mr. Chairman, I see the red light is on. I would like your permission for one more question, if I may?

Mr. TOWNS. Without objection.

Mr. SCHIFF. Thank you.

It is my understanding—I think we will be getting to this with other witnesses—that there was a lawsuit between the State of California—involving those in California, I am not sure who all the parties were, over the State of California saying that for chicken in the State of California, fresh means not cooled below, I think it is 26 degrees Fahrenheit.

It is further my understanding that the U.S. Department of Agriculture filed an amicus curiae brief in court against the Department of Agriculture, arguing that the Federal Government should preempt by their policy this issue and the State of California couldn't enforce its law.

First, am I right about that?

Mr. ROMINGER. Yes.

Mr. SCHIFF. I have to ask you this: I can think of no other example by this administration where they have entered a lawsuit saying a State could not provide a consumer protection label more stringent than the Federal Government otherwise mandates. So I am surprised that the Federal Government here in this case, the Agriculture Department, took a preemption by Federal law position.

Can you give other examples where the Federal Government has said the States can't do more to protect their citizens than the Federal Government might?

Mr. ROMINGER. First of all, I am not sure that I would agree that the California law is more stringent. But I will ask our legal counsel to answer the question.

Mr. GOLDEN. Yes, sir. Typically, we don't initiate amicus actions by being proactive in that area. We were asked by the court, by Judge Levi, in California on three occasions to provide an amicus brief in that proceeding. But the answer to your other question is that we did file an amicus in a case in Puerto Rico under a previous administration in which we claimed and pursued the notion of preemption of a Puerto Rican statute which imposed storage and

handling requirements and other requirements involved in the labeling and handling of poultry.

Mr. SCHIFF. So twice now you have entered amicus curiae briefs against States, or in this case our Commonwealth of Puerto Rico, dealing with poultry?

Mr. GOLDEN. I thought your question was centered on what was done during this administration. We have in other cases in previous administrations. We took, for example, the position that there was a preemptive effect of these same laws in communications between Governor Deukmejian in California and then Secretary Lyng, and in other cases in New York and California, we have over the years—I can provide you with citations, so to speak—we have taken the position that the statute preempts.

Usually those are cases in which we are brought into the proceeding in one way or another, as we were in this case. In this case, it might well have been that the parties themselves could adequately have briefed the issue of preemption. But when the court said in argument before the court that it liked to have a brief from the United States, and then sent a letter to the Justice Department asking for an amicus brief, and later issued an order in which he indicated his expectation that we would file a brief, since the question of preemption is at the core of a uniform Federal program for poultry and meat labeling, we felt that it was entirely proper for us—and I say us, I mean the Department of Agriculture and the Department of Justice—to file an amicus in this case.

But I would like to emphasize, if I could, that the amicus did not take any position with regard to the merits of the California law. It did not take any position that the California law was unreasonable. It simply took the position that as the statute says that any requirement of California that is "in addition to or different than the Federal requirement is preempted by Federal law."

Mr. SCHIFF. Mr. Chairman, I thank you for the additional time. I would agree that if the Department is invited to file a brief, that it would be appropriate to do so. But it was their choice to file the brief in favor of preemption and against States taking additional action to protect their citizens, and I find that surprising.

I yield back.

Mr. TOWNS. Thank you very much.

The gentleman's time has definitely expired.

At this time, I yield to Congresswoman Thurman.

Mrs. THURMAN. Good morning.

Mr. TOWNS. Good morning.

Mrs. THURMAN. Mr. Rominger, does the USDA issue any consumer guidance now regarding the refreezing of poultry products?

Mr. ROMINGER. Regarding which? I am sorry.

Mrs. THURMAN. Refreezing of poultry products.

Mr. ROMINGER. The safe handling labels indicate that the food should be handled, stored, and preserved, and refrigerated properly.

Mrs. THURMAN. But nothing on—when you say refrigerate, but maybe not refreezing?

Mr. ROMINGER. Mr. Medley.

Mr. MEDLEY. Congresswoman, we have a hotline in our Office of Consumer Affairs. We do have information addressing the issue of refreezing from a food safety perspective, and it does cover poultry as well as red meat.

Mrs. THURMAN. How does the consumer get that number?

Mr. MEDLEY. I should know it by heart. I will provide that information and the number. It is a toll-free number, and we do receive hundreds of calls weekly about all types of issues.

Mrs. THURMAN. Well, I think maybe, Mr. Medley, this panel would be very interested in knowing that number.

Mr. MEDLEY. Yes.

Mrs. THURMAN. And we could do some press releases in our district so they would have that information available to them.

Mr. MEDLEY. Yes. We will provide that.

[The information can be found in appendix 7.]

Mrs. THURMAN. Mr. Rominger, what is your best case scenario at this point for resolving the fresh issue for poultry? Is it 1 year from now? Is it more?

Mr. ROMINGER. I would certainly hope that it will be less than 1 year from now.

Mrs. THURMAN. And the last question: Would you have any problem with creating a third category of labels that would classify poultry products shipped in the zero to 24-degree range as fresh or frozen?

Mr. ROMINGER. We certainly will be examining all the alternatives, and that may be one of the solutions.

Mrs. THURMAN. Thank you.

Mr. TOWNS. At this time, I yield to Congressman Mica.

Mr. MICA. Thank you, Mr. Chairman.

Mr. Rominger, I asked you at the last hearing of our subcommittee that you attended if you had ever lied to or purposely misled a Member of Congress, and I will ask you the same question again. Have you lied to or purposely misled a Member of Congress?

Mr. ROMINGER. I have not.

Mr. MICA. Have you made false statements to a Member of Congress?

Mr. ROMINGER. No, sir.

Mr. MICA. Are you familiar with Federal Statute 18 U.S. Code 1001, which is the Federal False Statement Statute?

Mr. ROMINGER. I am not intimately familiar with that; no.

Mr. MICA. Mr. Rominger, I had asked for some information from you before at the last hearing, and I asked for it on a specific date and it didn't come on that specific date. I said I would conduct a Freedom of Information Act request, and I did a Freedom of Information Act request.

From the records that I obtained, Mr. Rominger—and you are under oath—did you go to California in September——

Mr. TOWNS. Would the gentleman yield?

I hate to interrupt the gentleman for whom I have great respect, and who is a very effective member of this committee, but the issue that you are raising is not before us today.

Mr. MICA. Well, it is, sir, because it deals with the credibility of this Department. My next issue leads into it, but if I may, sir, just let me finish asking my question.

On September 9 and 10, did you go to California for personal or business purposes?

Mr. ROMINGER. Yes, I did.

Mr. MICA. For both purposes?

Mr. ROMINGER. Yes.

Mr. MICA. Thank you, sir.

Mr. Rominger, it is my understanding the committee requested information from you and answers to our questions that were supposed to be due on the 14th, and we received this at 9 o'clock last night. Is that correct? Were these provided to the committee last night at 9 o'clock?

Mr. ROMINGER. I am not sure what time they arrived. We were—yes—waiting to hear from the committee.

Mr. MICA. Well, I just got them this morning.

Mr. Chairman, I ask unanimous consent that the record be left open for Members to submit to Mr. Rominger in writing questions relating to the statement that he delivered late to this committee.

Mr. TOWNS. Without objection, we will hold the record open for 10 days.

[The information can be found in appendix 7.]

Mr. MICA. Mr. Rominger, I want to ask you some questions about the information dealing with the conduct of your specific Department and also higher administrative levels in the Department.

Can you provide this committee with communications, a list of meetings, and telephone calls between you and the administrators in the Department between January 20, 1992, and June 1, 1994? Are there communications—and the other items I mentioned—dealing with Tysons Food or Arkansas Poultry Federation, and in particular, any communications, direct or in writing, on meetings that you had between September 23, 1993, and April 1, 1994?

Mr. ROMINGER. I would be happy to do that.

Mr. MICA. Thank you. Would it be possible to have those by July 1, by close of business, which is 5 o'clock?

Mr. ROMINGER. Yes, sir.

Mr. MICA. OK. Thank you.

[The information can be found in appendix 7.]

Mr. MICA. In a court dispute over labeling, the Department of Agriculture took the side of Arkansas over California, and it is my understanding that there was a request from the court that the Department of Agriculture join in that. Is that correct?

Mr. ROMINGER. We were requested to file an amicus, yes.

Mr. MICA. Were there any other communications between either of the two entities; the Tysons Food or Arkansas Poultry Federation, requesting that action?

Mr. ROMINGER. Not that I am aware of.

Mr. MICA. Is there or has there been any legislative recommendation to this committee or to Congress to amend the Poultry Act or to change the procedures by which poultry is labeled "fresh" since you have been in office?

Mr. ROMINGER. Any legislative proposals?

Mr. MICA. Yes.

Mr. ROMINGER. Not to my knowledge, no.

Mr. MICA. Or any other proposals to the Congress?

Mr. ROMINGER. Not to the Congress, no. We are doing the hearings that I announced this morning and will be making recommendations as a result of that.

Mr. MICA. My time is up.

Mr. Chairman, I have additional questions I would like unanimous consent to submit also for the record.

Thank you.

Mr. TOWNS. Without objection, the gentleman will be able to submit the additional questions.

At this time, I would yield to Congressman Payne.

Mr. PAYNE. Thank you very much, Mr. Chairman.

Let me just ask a question, Mr. Rominger. Why is it that regulations on labeling poultry frozen are more stringent than regulations labeling those products fresh?

Mr. ROMINGER. Did you get the question, Terry?

Mr. MEDLEY. No, I didn't.

Mr. ROMINGER. Why are the labels on poultry——

Mr. PAYNE. I will repeat it. Why is it that regulations for labeling poultry fresh are more stringent than regulations labeling these poultry products—labeling them frozen, why is it more—so now you have me confused. [Laughter.]

Hold on. First you didn't know anything. Then you confuse a Congressman.

Let me go again.

Mr. TOWNS. Welcome to the club.

Mr. PAYNE. Why is the regulation on labeling poultry frozen more stringent than regulations labeling these products fresh?

Mr. ROMINGER. I didn't mean to characterize that that was more strict, but I didn't think that the other was more strict either. I think we are evaluating those now in looking again at what the scientific literature says and what the consumer's perception is, so that we can make the appropriate changes.

Mr. PAYNE. OK. Let me just say one other thing.

In your written statement, you state that consumers are not simply concerned with whether or not a food product is labeled as fresh. They also demand and deserve food that is safe, but I think you missed the point.

Consumers want safe food. They also want food that is honestly labeled. If poultry needs to be chilled to a certain temperature to be handled safely, then require it to be properly chilled, but also require that the label honestly reflect the product.

Why should consumers have to tradeoff honest labeling for product safety or vice versa?

Mr. ROMINGER. We hope as a result of our review at the present time that that will not be the case. There will not have to be a tradeoff. That we will be able to do both.

Mr. PAYNE. I am also really concerned about the policy behind this labeling issue, and I want to stick with the labeling issue. I don't think that these other extraneous issues—where you went and who you called—are important.

I want to deal with the safety of food to people in this country, and I want to discuss how this labeling policy is formulated.

Now, there is a public health issue involved here. Recently, the Department has required producers to attach handling instructions

to poultry and meat. If labels are not accurate, then how can you assume that the handling instructions would be commensurate with what is on the label?

Wouldn't you find this a little bit confusing?

Mr. ROMINGER. We want consumers to have the information that they need, and that is why we are surveying consumer perceptions, so that we will be able to make sure the consumer understands what the package contains and how it should be safely handled, prepared, and stored.

Mr. PAYNE. I believe that Vice President Gore issued a recommendation, that all food safety inspection responsibilities be transferred to the Food and Drug Administration; it is one of his recommendations in his report on reinventing government. Has your Department taken a position on this?

Mr. ROMINGER. At the present time, this responsibility is with the Department of Agriculture and Secretary Espy has been intimately involved since the first day he was Secretary of Agriculture as a result of those E. coli outbreaks. So he wants to make sure that we are doing the best job possible, as long as it is at the Department of Agriculture.

It will be up to Congress to make the final determination on where the inspection should reside. We will abide by that ruling, of course.

Mr. PAYNE. Well, let me just say that, first of all, I think that Secretary Espy has come into the Department and he was beset with a number of immediate problems, and I think that he handled them very well, as related to red meat and the temperature at which hamburgers are cooked, whatever it was—and really put everything in effect to make sure that consumers were protected.

We have a very strong food and food products industry in this country, and the world marvels at that. I think that we have a responsibility to make sure that people have confidence. Once you lose confidence—we saw it in the auto industry. People lost confidence in U.S.-made cars 15 or 20 years ago, so they went to buy cars from other places that they felt were safe, that were better built, that were more economical. We would hate to see the U.S.A. lose its position as producers of safe food in an economic way.

I think that it is incumbent upon the industry to ensure accuracy in labeling, as Mrs. Thurman mentioned, just put it is frozen, almost frozen, and fresh.

You know, let people decide what they want. I don't see that as being—I think that a cloud is brought over the industry unnecessarily. Just have the categories labeled. Make it clear and simply let people select based on accurate information.

I don't think it would have any impact on the industry. There may be a little difference in pricing, but people will be able to buy what they want.

So my point is we have an industry that is one of the premier industries, our food industry in this country. We are seeing that problems are coming in, so my appeal is that we continue to have the leadership in the world as it relates to food and food products; that we have the confidence of the people, because it is important, and our constituents deserve that.

So, Mr. Chairman, I have an opening statement that I would ask unanimous consent to have enter into the record.

Mr. TOWNS. Without objection, the gentleman's entire statement will be included in the record.

Let me just also share with him that his time has now expired.

[The prepared statement of Mr. Payne follows:]

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Rep. Donald Payne
--Opening Statement--
Human Resources and Intergovernmental
Relations Subcommittee
"Fresh v. Frozen Chickens"
June 16, 1994

Good Morning. Mr. Chairman, I would like to commend you for your leadership in calling this hearing today. I would also like to extend my regards to the panel of witnesses who have agreed to provide us with their testimony.

Last month, we held a hearing on the FDA capacity to manage its food safety responsibility of seafood. Today, we are back dealing with the subject of poultry labeling standards issued by the Department of Agriculture.

I can't stress enough the importance of ensuring that our food supply is among the safest in the world and maintaining the public's confidence in our ability to do that. I believe that honesty in labeling is the best way to achieve that.

Current Department of Agriculture regulations differ on the definitive requirements applied to labeling poultry frozen or fresh. The USDA does not define the term "fresh" for poultry, nor do they require that products be labeled as "fresh". However, USDA regulations define the term "frozen" and limit the use of the term on labels.

There is a larger issue to consider and that is the public health issue and our responsibility to ensure it. If the product is not labeled accurately, then the public does not receive the appropriate safety and handling instructions that should accompany purchase. As a consequence, there is a potential health risk. If you think about it, it's no wonder that chicken is responsible for the majority of food borne illness in this country.

This subcommittee has held two previous hearings examining Vice President Gore's recommendation that all food safety inspection responsibility be transferred to the Food and Drug Administration. During these hearings we uncovered some very disturbing practices in the meat inspection process and the policy governing this process. I'd be interested in gaining insight to how policy regarding this very important function is formulated.

Because, in holding these hearings, this subcommittee is trying to prevent another tragic outbreak like the E. coli outbreak that took place on the West Coast in November 1992.

Mr. Chairman, I would like to again thank you for your leadership on this very important issue and I look forward to hearing the testimony of the witnesses.

Mr. ROMINGER. Could I comment, Mr. Chairman.

Mr. TOWNS. Yes.

Mr. ROMINGER. I would just like to say that we did inherit some of these problems when Secretary Espy arrived, such as the labeling and the changes that were made in definitions over the years back and forth, and Secretary Espy is the one who wants to open this up and wants consumers to be heard before we make a decision on what should be appropriate.

Mr. TOWNS. Thank you.

Congressman Horn.

Mr. HORN. Thank you very much, Mr. Chairman.

Mr. Secretary, I regret your testimony was not available to us until after the hearing started, on our side, and we have not had an opportunity to analyze every aspect of it, so we are going to take advantage and, perhaps, send you some questions.

But one thing struck me here that we have already discussed, and in your testimony on page 3, you note that on July 11, 1988, Secretary Richard Lyng's administration issued policy memo 022B which would have prohibited the use of the term fresh in conjunction with any poultry product that was chilled or had been previously chilled, so on and so the forth.

Then it turns out that was issued, but it was never implemented, as your testimony states, and 6 months later, on January 11, 1989, after receiving comments from some members of the poultry industry, the food inspection—Food Safety and Inspection Service issued policy memo 022C, which, in essence, is what you have now, as I understand it.

Mr. ROMINGER. Correct.

Mr. HORN. Well, I am curious. One, this occurred under the Reagan administration. I am interested, if Secretary Lyng is still available, Mr. Chairman, I would like this committee to write him and get his sense of why they issued it, but it was never implemented. Was that a decision by the Secretary? Was that by a decision of the Food Safety and Inspection Service. What caused that?

Was this simply the bureaucracy at the end of one administration sort of taking over and ignoring the Secretary's policy memo?

I will hope we could pursue that and get that information from the person that was there whether there was an attempt to change the policy. Nothing ever happened to it. It wasn't implemented, according to the Deputy Secretary, and the policy that was implemented happened a few days before President Bush took office.

So I just think we ought to clarify the record on were these receiving comments from some members of the poultry industry are we talking about two people? Are we talking about 2,000? Are we talking about Members of Congress representing various interests or what?

I would just like that to be clarified.

Mr. TOWNS. Without objection, so ordered.

Mr. HORN. All right.

[The information can be found in appendix 7.]

Mr. HORN. Now, let me ask Mr. Golden on the amicus brief bit. I have been involved as an educator with filing numerous amicus briefs with national associations on one side or the other. Usually when you get into this, one of the parties comes to you and says

"We would like you to file a brief because we know you, as a government agency, or a national professional association, will have credibility above the battle of the contending special interests on either side."

Now, you said the judge asked for the amicus brief, as I heard your testimony.

Mr. GOLDEN. That is right.

Mr. HORN. Did the Secretary of Agriculture or anyone in his office or any Members of Congress ever suggest to you that an amicus brief be filed in the California case?

Mr. GOLDEN. Sir, I believe the history of that issue is that after the—after we became aware of the lawsuit, we were contacted by various people who were involved in the lawsuit.

Mr. Saferstein, who represented the California Poultry Industry Federation contacted us, and the attorneys for the National Broiler Council also contacted us, and both sides were arguing regarding the amicus brief. They argued either that we should file an amicus brief on their behalf or if we wouldn't do that, that we should not file an amicus brief.

At that point, it was the disposition of the Department not to file a brief because the parties were well represented by very able counsel on both sides and we really didn't see at that point that there was any particular issue that couldn't be explored by the court, particularly since Judge Levi seemed, from the hearing that he had conducted, very knowledgeable on the issues and on the preemption question and so on.

But when the court then specifically requested that we file a brief, first by suggesting it in the course of the hearing; second, by a letter, and then later by referring to it in an order, we felt that it was incumbent on us since this is a core issue in our program to file a brief.

I believe that the parties, the California parties represented by Mr. Saferstein, I know they met with our general counsel. I know they met with the Assistant Secretary, and I know they met with the Deputy Secretary. And I believe the other side met with the Assistant Secretary.

Mr. HORN. What was the level of final approval within the Department that you would submit an amicus brief and what the general thrust of it would be?

Mr. GOLDEN. There was never a question about what position we would take in an amicus brief. The position that anything that is in addition to or different than the Federal requirement is preempted is a position which we have long held and which is really unobjectionable. So that was not really——

Mr. HORN. Have you ever made an exception to that position?

Mr. GOLDEN. I don't think so, sir.

Mr. HORN. Not in your lifetime——

Mr. GOLDEN. Not in my lifetime.

Mr. HORN [continuing]. Of 20 years in Federal service?

Mr. GOLDEN. Well, 10 years—11 years here.

Mr. HORN. Eleven years at Agriculture.

Mr. GOLDEN. No, but the Justice Department, attorneys in the Civil Division, an attorney in my office, Mr. Safian, was working with people in the Justice Department, and the Justice Department

people attended some of the sessions when outside counsel came in to discuss the issue. And it was finally decided by the policy administration of the Department that we should go ahead to file a brief.

In effect, it would be odd considering the request of the court if we did not do so.

Mr. HORN. In other words, you mentioned it did rise at least to the Deputy Secretary's level. Was that Mr. Rominger?

Mr. GOLDEN. Yes, sir.

Mr. HORN. Or did it go to the Secretary also?

Mr. GOLDEN. I think maybe Mr. Rominger could address that.

Mr. HORN. Did you consult with the Secretary?

Mr. ROMINGER. Yes. To the best of my recollection, the Secretary did make the decision that we should file a brief and agreed with our general counsel.

Mr. HORN. OK. So he was following the basic departmental policy, in your mind?

Mr. ROMINGER. I think he was aware that the court asked for the amicus brief and that he agreed with our general counsel that we should proceed to file one.

Mr. HORN. And he agreed with the policy request implication of that brief, I take it? Or did he say, since he is very consumer oriented, "Hey, wait a minute, I think you are dead wrong in Agriculture."

If some State has tougher rules to help the consumer, we ought to be backing it. I mean that is a choice the Secretary has.

Mr. ROMINGER. Well, as I recall the discussion, we decided we had to uphold the Federal preemption issue, but at the same time, as Mr. Golden has indicated, we did not comment on the California law, and we moved right after that to review the whole issue.

Mr. HORN. One last question on policy memos, since I had mentioned them, with the Lyng administration.

Our committee staff apparently in discussing all of these matters with the U.S. Department of Agriculture staff got the feeling from Agriculture staff that policy memos do not have the force of law, and in fact they don't even have the strength of a regulation.

What is the penalty for failing to comply with a policy memo such as was issued by Mr. Lyng?

Mr. GOLDEN. The policy memos in this area, sir, are memos which are intended to interpret and set out agency policy with regard to the interpretation of a particular regulation. They are not—without the underlying regulation, they certainly are not enforceable law. But as interpretations of an existing regulation, they are given weight by the courts. But they are not regulations themselves.

Mr. HORN. Now, I take it policy memo 022C has been implemented by regulation; is that correct?

Mr. GOLDEN. No, sir.

Mr. HORN. Well, what is the status of that? I mean, that is still your policy.

Mr. GOLDEN. The Poultry Products Inspection Act is an act which provides for individual decisions on labels. The statute requires that the Secretary of Agriculture approve labels in advance, and so the labels are submitted before they can be used. They can-

not be used unless they are submitted and approved by the labeling division within the Food Safety and Inspection Service.

When the Food Safety and Inspection Service reaches a decision on a label, if they decide not to approve the label, there are internal appeal processes within the agency, and the aggrieved party is entitled to a hearing before an Administrative Law Judge on the label.

So there is a process, an adjudicatory process within the agency on these labels.

From time to time, the agency will, in effect, summarize its view of what its regulations and what its individual adjudications have created as a policy and issue that in the form of a policy memorandum. I believe that is the status of the policy memorandum.

It is different—it is somewhat different than policy memorandums that are issued in other areas, because here the party who files the label also has the right to an adjudicative process within the agency.

Mr. HORN. So it does have some meaning?

Mr. TOWNS. I hate to interrupt the gentleman from California, but the red light is on and the gentleman's time has expired.

At this time, I yield to Congressman Peterson.

Mr. PETERSON. Mr. Chairman, I just want to thank you and Chairman Condit for allowing me to join your committees this morning. This issue doesn't have a direct affect on us in Minnesota, but our State and my district has some of the most production in turkeys and chicken in the country, and so I have an interest in this issue.

I am here mostly to learn, so I appreciate being able to be with you, but I won't take any time of the committee.

Mr. TOWNS. Thank you very much. Delighted to have you join us as well.

Congressman Portman.

Mr. PORTMAN. Thank you, Mr. Chairman.

My 1-year seniority gets me ahead of Mr. Lucas here, I suppose.

I thank you all for being here this morning. I have a few questions, really followup to previous questions and some of the testimony I have heard today.

The first really goes to the whole issue of legislation versus regulation. You talked some about the research triangle report that was submitted to us during your testimony. I haven't had a chance to analyze it carefully, but it appears that two points made in this research triangle report are that there are inconsistencies between meat inspection and poultry inspection because of the different products, but also because of the fact that the laws were passed at different times—the Poultry Act in 1957; the Meat Act in 1907.

The inference I draw from that is that you all may, in fact, be looking for some more legislative guidelines or statutory guidelines.

You then went on, Mr. Rominger, later in your remarks, and I believe in Mr. Medley's as well, in response to questions from previous Members, to say that the hearings which you are undertaking, I think they are FSIS hearings to be held shortly, may, in fact, lead to some new legislative remedies.

I don't know if I heard you correctly on that. But is it your sense, in fact, what we need here is not the promulgation of new regula-

tions, but in fact a new law with regard to inspection, particularly in the poultry side?

Mr. ROMINGER. First of all, let me say that those laws were implemented a number of years ago, I believe. They have been amended a number of times since then. But as far as our review goes, we haven't prejudged that.

We don't know whether we will decide that we can do it with a policy memo, with new regulations, or whether it will require legislation. We have not made that decision yet.

Mr. PORTMAN. OK.

While I have you here, I would like to ask a couple of other questions that may come up later when other panelists raise them, and perhaps you would like the opportunity to respond now. One is the—what I view as the inherent conflict that arises between USDA's responsibilities in promoting marketing agriculture on the one hand, and on the other hand, inspecting agriculture.

This has been the subject, general subject, I think it is fair to say, of two previous subcommittee hearings, of the Towns subcommittee.

I would like your view, Mr. Rominger, whether you think, in fact, USDA should continue in its food safety role, particularly with regard to poultry products.

Mr. ROMINGER. We believe that we can do both regulation and promotion. We have different agencies in the Department that operate those different functions, and the Secretary is certainly committed to a strong meat and poultry inspection program as long as it is at the Department of Agriculture.

We believe that we can do a good job, and one of the reasons is because we do have a relationship with the agricultural industry, with the producers so that we can go on to the farms and begin the pathogen reduction program on farms; that we have a relationship.

We have the veterinarians there who can better do this than other agencies.

Mr. PORTMAN. And that would be the HACCP program that you discussed earlier?

Mr. ROMINGER. It would be HACCP or it would be our pathogen reduction program, where we actually go on farm and look at problems there and assist the ranchers with any disease problem so that they don't get carried on up the food chain.

Mr. PORTMAN. Notwithstanding the Vice President's report, then it is the official view of the Department that the Department should continue to have the existing roles with regard to food safety?

Mr. ROMINGER. We believe we can do a good job and would like to keep it there, but we will certainly abide by whatever the decision is.

Mr. PORTMAN. OK.

One final question that has to do with the California case. I haven't practiced law for a year or so, so I am forgetting some of this, but it seems to me with Federal preemption normally the reason you would get involved to do an amicus brief in this case would be because there is an inconsistent State law with the Federal law.

Is that your view, Mr. Golden.

Mr. GOLDEN. With regard specifically to the labeling provisions in the California law, they were in addition to requirements of the Federal program, and the Poultry Inspection Act does not speak simply about conflict in a sense of difference, but it says that a State shall not impose a labeling requirement that is "in addition to or different than," so it is in addition to or different than the Federal requirement.

We viewed this requirement as meeting that statutory standard.

Mr. PORTMAN. OK.

My point, of course, is that one could certainly look at the California law as not being inconsistent with the Federal law. In fact, one could say the Federal law was silent on the issue of frozen.

Mr. GOLDEN. There are some statutes where the question is that the State can legislate as long as it is not inconsistent with, as long as it is supportive of the Federal law, but this statute is very specific to entirely preempt the field, so to speak, and hold that any requirement, in addition to or different than, the Federal requirement is preempted.

Mr. PORTMAN. Even when not inconsistent with the objectives of the Federal law or regulations?

Mr. GOLDEN. That is correct.

Mr. PORTMAN. Having heard from Mr. Medley earlier about the objectives and the goals, those kind of broad principles would seem to be inconsistent to me—would seem to be consistent to me with what California was trying to do.

Mr. GOLDEN. That may be. I would like to underscore that we did not take a position on the merits of the California law. In fact, it was within the same week that we filed our brief that the Secretary issued his press release saying that he wanted this issue to be reexamined in light of consumer perceptions and food safety.

So all the meetings that we had with the California representatives and so on were very sympathetic to the issue and certainly did not in anyway denigrate the merits or address the merits of the California law.

Mr. PORTMAN. OK. Thank you.

I yield back, Mr. Chairman.

Mr. TOWNS. Thank you very much.

At this time, I yield to Congressman Barrett.

Mr. BARRETT. Thank you, Mr. Chairman.

I simply want to commend you for holding this hearing. I know we have a busy schedule today, so I will refrain from any questions and yield back the balance of my time.

Mr. TOWNS. Thank you, Mr. Chairman. Thank you very much.

At this time, I yield to Congressman Lucas, a new member of this committee. We are delighted to have you.

Mr. LUCAS. Thank you, Mr. Chairman.

Of course, having been a member of this body as a whole for just a very few weeks now, and a member of this committee for a very few days, I have been impressed by the mountains of material to be absorbed and the work to be done.

A couple of brief questions to the Secretary.

Listening earlier to some of the questions by one of my colleagues, if I understood the logic correct, and I think he was speaking in regard to the fecal contamination question, did I understand

you, in essence, to say that even though the law that pertained to beef was 50 years older than the one that pertained to poultry, that the standards were more, or the regulations, in effect, were more restrictive, I guess would be the language; held the contamination toleration to a lower level on beef?

Mr. MEDLEY. I am not following the question. I am sorry, Mr. Lucas.

Mr. LUCAS. If I understood the logic of one of my colleague's that the law—and he was speaking in regard, I believe, to fecal contamination, but I was given the impression from the responses and all that although the law that pertains to beef was 50 years older than the one that pertains to poultry, in fact, it held beef to a lower acceptable level of contamination, if any, in that subject.

Did I understand that correctly?

Mr. MEDLEY. I think that the statement was that the enforcement and the zero tolerance was more restrictive.

Yes.

Mr. LUCAS. OK. One other question. We have discussed the beef industry and the poultry industry today, but just for my background, in comparison, how do the pork standards or the standards that regard fish compare to the regulations that we have in regard to beef and poultry?

Mr. MEDLEY. With regard to pork, it is within the beef category, what we call red meat——

Mr. LUCAS. And with regard to fish.

Mr. MEDLEY. That is not covered under our program.

Mr. LUCAS. OK. And the fish are covered by who?

Mr. MEDLEY. The Food and Drug Administration.

Mr. LUCAS. FDA. OK. Thank you.

Thank you, Mr. Chairman.

Mr. TOWNS. Thank you very much.

Let me just say before we dismiss this panel that the record will be held open for 10 days, and that there are some additional questions that we would like to submit in writing to you and we hope to get a response within that period of time.

Let me thank you for your testimony, Mr. Medley, Mr. Rominger, and Mr. Golden. Thank you very much.

[The information can be found in appendix 7.]

Mr. TOWNS. At this time we will call on our second panel, Mr. Henry Voss, Secretary of the California Department of Food and Agriculture; and the world-renowned chef extraordinaire, Mr. Wolfgang Puck. Please come forward.

Is that fresh? [Laughter.]

Before we begin, I would like to say to Mr. Voss and to Mr. Puck, and all of our remaining witnesses, that your entire statements will be included in the record, and if you just could summarize within 5 minutes, that would allow the members of the panel to raise questions, and I would appreciate it.

It is the custom of the Government Operations Committee to ask that all witnesses who present testimony be sworn in. So may I ask both of you to stand and raise your right hand.

Do you swear to tell the truth, the whole truth, and nothing but the truth? If so, answer in the affirmative.

[A chorus of "I do."]

[Witnesses sworn.]

Mr. TOWNS. Thank you. You may be seated.

Let the record reflect that both of them have answered in the affirmative.

Let me thank you very, very much for coming.

Mr. Voss, why don't we start with you. Welcome.

STATEMENT OF HENRY J. VOSS, SECRETARY, CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

Mr. VOSS. Thank you, Chairman Towns, Chairman Condit, and members of the committee. It is my pleasure to be here as Secretary of the Department of Agriculture of California.

With me in the audience is the secretary of our Consumer Service Agency in California, Secretary Joanne Kozberg. She has submitted her testimony in writing, but is here if there should be a question in a consumer nature that she could answer.

Thank you for inviting me to testify today on the fresh poultry labeling controversy. In my opinion, few issues are more clearcut than this one.

Let me start by saying that in September 1993, our legislature passed and Governor Pete Wilson signed section 6661 of the California Food and Agriculture Code, otherwise known as the California Fresh Poultry Consumer Protection Act. This was the only piece of legislation to pass during the entire legislation session on a unanimous bipartisan vote.

What the law said, in essence, was that poultry producers, both in State and out of State, could not mislead consumers by calling poultry products fresh if they had been frozen or previously frozen before sale.

The law accurately cited the fact that poultry at 26 degrees Fahrenheit is between fresh and frozen poultry. In other words, any chicken chilled below 26 degrees would not be mislabeled fresh under the California law.

The 26-degree threshold was not some arbitrary temperature, as the National Broiler Council has charged. It is the actual freezing point for poultry according to Mother Nature, and even the U.S. Department of Agriculture's own food inspection personnel.

In 1988, the U.S. Food Safety and Inspection Service conducted a study and determined that many of the large national poultry producers routinely freeze chicken, but then label it fresh before sale. The agency also found that when chicken is chilled below 26 degrees, it becomes very cold, hard to the touch, solid on the inside and full of icicles.

In other words, it becomes frozen, and once it is frozen, it is no longer fresh.

This Federal agency issued policy memorandums. It has already been talked about, so I will move along.

Indeed the reason the food safety agency reversed itself in 1989 without any public hearing is that the powerful National Broilers Council flexed its muscle. The broiler council is dominated by the National Poultry Producers based in the southern States.

These are the giant producers of the industry who make billions deep-freezing chicken, shipping it throughout the country, thawing it out at local distribution points, and then selling it with "fresh"

labels on the package to consumers who are willing to pay higher prices for fresh, not frozen, food.

In my view, this practice is nothing less than outright fraud, and the fact that it is sanctioned by the Federal Government is scandalous. I believe consumers have the right to know that the food they purchase is really fresh or whether it has been frozen.

There is nothing necessarily wrong with frozen food, but producers shouldn't be able to mislead consumers into paying a higher price for a product they believe is fresh, and are being told is fresh when, in fact, it has been frozen, often for weeks at a time, and then thawed out.

Like many other States, California has a long history of enforcing tough consumer protection laws. We believe producers wherever they are located should be honest with the consumer. That is why we passed the poultry law last year, and why we based our 26-degree standard on USDA studies from 1988.

We took action at the State level because we became frustrated with the Federal flip-flop on this issue and with the increasing amount of frozen poultry that is being shipped into our State and sold under fresh pretenses.

Our law is not as some have claimed protectionist or discriminatory in anyway against out-of-State competitors. Rather, it is designed to protect consumers from false advertising by producers wherever they are from.

Out-of-State producers could easily ship fresh poultry to California at safe, nonfrozen temperatures, and many do. Unfortunately, we never had an opportunity to enforce the main part of our law, because the Broiler Council, the American Meat Institute, and even the powerful Arkansas Poultry Federation, sued us. They argued that States as a matter of law cannot pass more stringent food labeling requirements than the Federal Government.

In December, a Federal court issued a preliminary injunction later made permanent. We have appealed that and in July, the circuit court will hear our expedited appeal.

Our view is that California has every right to protect its consumer in this regard. As a legal matter, we do not think our law is preempted by the Federal poultry producers inspection act as the lawsuit claims. This law requires producers to disclose certain information on food labels, weight, content and the like. The law says that States cannot pass food labeling requirements that are different from or in addition to Federal requirements. But our law doesn't require producers to put anything additional on labels. It does not require frozen chickens to be labeled frozen, and moreover, our law is not different from the Federal act because the Federal act does not say a word about fresh or frozen. How can we preempt the Federal law on Federal poultry when there really is no Federal law on the subject.

The California statute is not, technically speaking, a food labeling requirement. All it says is that when a producer for marketing purposes voluntarily puts the word "fresh" on a label, States have the right to prohibit this from being done in a misleading and deceptive fashion.

To consumers, all this legal mumbo-jumbo is beside the point. To them the issue is really quite simple: fresh is fresh, frozen is frozen, and food that had been frozen is no longer fresh.

I am hopeful that California will prevail in its legal case. But whether we do or not the Federal Government has an obligation to ensure that its own food labeling standards are accurate to not only the producers, excuse me, are accurate and do not allow producers to mislabel food to deceive consumers. However, if USDA fails to raise the Federal standards to 26 degrees, I would encourage Congress to do it through legislation and/or to amend the Poultry Product Inspection Act to expressly allow States to adopt freshness standards of their own.

Thank you.

Mr. TOWNS. Thank you very much, Mr. Voss for your testimony.

[The prepared statement of Mr. Voss follows:]

TESTIMONY OF HENRY J. VOSS, SECRETARY
CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
BEFORE THE GOVERNMENT OPERATIONS SUBCOMMITTEES
ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS
AND
INFORMATION, JUSTICE, TRANSPORTATION AND AGRICULTURE

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, D.C.
JUNE 16, 1994

Thank you, Chairman Towns, Chairman Condit and Members of the Committee. My name is Henry J. Voss and I am Secretary of the California Department of Food and Agriculture.

Thank you for inviting me to testify today on the fresh poultry labeling controversy. In my opinion, few issues are more clear-cut than this one.

Let me start by saying that in September of 1993, our Legislature passed, and Governor Pete Wilson signed, Section 6661 of the California Food and Agriculture Code, otherwise known as the California Fresh Poultry Consumer Protection Act. This was the only piece of legislation to pass during the entire legislative session on a unanimous, bipartisan vote.

What the law said, in essence, was that poultry producers, both in-state and out-of-state, could not mislead consumers by calling poultry products fresh if they had been frozen or previously frozen before sale.

The law accurately cited the fact that poultry at 26 degrees Fahrenheit is between fresh and frozen poultry. In other words, any chicken chilled below 26 degrees could not be mislabeled fresh under the California law. The 26-degree threshold was not some arbitrary temperature, as the National Broiler Council has charged. It is the actual freezing point for poultry, according to Mother Nature and even the U.S. Department of Agriculture's own food inspection personnel.

In 1988, the U.S. Food Safety and Inspection Service conducted a study and determined that many of the large, national poultry producers routinely freeze chicken, but then label it fresh before sale. The agency also found that when chicken is chilled below 26 degrees, it becomes very cold, hard to the touch, solid on the inside and full of ice crystals.

In other words, it becomes frozen. And once it's frozen, it's no longer fresh.

This federal agency then issued a policy memorandum stating that producers should not falsely label as fresh any poultry product that had been frozen or previously frozen below 26 degrees Fahrenheit. This was policy memorandum No. 022-B and it was issued on July 11, 1988.

Exactly six months later, on January 11, 1989, the agency abruptly reversed itself by issuing policy memorandum No. 022-C. This policy memo restored the old standard which said producers could freeze chicken to **zero degrees** Fahrenheit and still call it fresh.

Indeed, the reason the food safety agency reversed itself in 1989, without any public hearings, is that the powerful National Broiler Council flexed its muscle. The Broiler Council is dominated by the national poultry producers based in southern states. These are the giant producers who make billions deep freezing chicken and shipping it throughout the country, thawing it out at local distribution points and then selling it with fresh labels on the packages to consumers who are willing to pay higher prices for fresh, nonfrozen food.

In my view, this practice is nothing less than outright fraud, and the fact that it is sanctioned by the federal government is scandalous.

I believe consumers have the right to know if the food they purchase is really fresh or whether it has been frozen. There is nothing necessarily wrong with frozen food, but producers shouldn't be able to mislead consumers into paying a higher price for a product they believe is fresh -- and are being told is fresh -- when in fact it has been frozen, often for weeks at a time, and then thawed out. Transporting frozen poultry products long distance is appropriate to ensure food safety.

Like many other states, California has a long history of enforcing tough consumer protection laws. We believe producers, wherever they are located, should be honest with consumers. That is why we passed the poultry law last year, and we based our 26-degrees standard on the USDA study from 1988. We took action at the state level because we became frustrated with the federal government's flip-flop on this issue and with the increasing amount of frozen poultry that is being shipped to our state and sold under fresh pretense.

Our law is not, as some have claimed, protectionist or discriminatory in any way against out-of-state competitors. Rather it is designed to protect consumers from false advertising by producers wherever they are from. Out-of-state producers

could easily ship fresh poultry to California at safe, nonfrozen temperatures, and many do. The fact that some giant producers prefer to freeze their chicken to have maximum time flexibility is not our fault. But it is our responsibility, when they sell frozen poultry in our state, to prevent them from misrepresenting their products and taking advantage of our consumers.

Unfortunately, we never got an opportunity to enforce the main part of our law because the Broiler Council, the American Meat Institute and the ever powerful Arkansas Poultry Federation sued us. They argued that states, as a matter of law, cannot pass more stringent food labeling requirements than the federal government.

In December, a federal district court issued a preliminary injunction against California's statute. In February, the U.S. Department of Agriculture filed a brief supporting the challenge to our law on jurisdictional grounds, although Secretary Espy also said at the time that he would review the federal policy to make sure it "meets today's consumer expectations." I am told his review is still pending, but no official rulemaking or public hearings have been scheduled to my knowledge, and our Department received only a single phone call to discuss the matter.

In April, the federal judge who initially ruled against our law made his injunction permanent, but in July the circuit court will hear our expedited appeal.

Our view is that California has every right to protect its consumers in this regard. As a legal matter, we do not think our law is preempted by the federal Poultry Products Inspection Act, as the lawsuit claimed. This law requires producers to disclose certain information on food labels -- weight, content and the like. The law says that states cannot pass food labeling requirements that are "different from or in addition to" federal requirements.

But our law doesn't require producers to put anything additional on labels. It does not require frozen chicken to be labeled frozen. Moreover, our law is not different from the federal Act because the federal Act does not say a word about fresh or frozen. How can we preempt the federal law on fresh poultry when there really is no federal law on this subject.

The California statute is not, technically speaking, a food labeling requirement. All it says is that when a producer, for marketing purposes, voluntarily puts the word fresh on a label, states have the legal right to prohibit this from being done in a misleading or deceptive fashion.

To consumers, all this legal mumbo-jumbo is beside the point. To them, the issue is really quite simple. Fresh is fresh and frozen is frozen. And food that has been frozen is no longer fresh.

We are very disappointed that USDA chose to enter the lawsuit against California. We note that several other states, including New York, have Kosher laws that deviate from federal standards. But USDA has not gone to court to challenge New York or other states with fresh laws similar to our own.

I am hopeful that California will prevail in the legal case. But whether we do or not, the federal government has an obligation to ensure that its own food labeling standards are accurate and do not allow producers to deliberately deceive consumers. USDA should immediately adopt an enforceable rule that mirrors the 26 degrees standard so that frozen chicken will no longer be mislabeled fresh.

However, if USDA fails to raise the federal standard to 26 degrees, I would encourage the Congress to do it through legislation and/or to amend the Poultry Products Inspection Act to expressly allow states to adopt freshness standards of their own.

I would be happy to answer any questions.

Mr. TOWNS. At this time, Mr. Puck.

STATEMENT OF WOLFGANG PUCK, WORLD-RENOWNED CHEF EXTRAORDINAIRE

Mr. PUCK. Thank you, Mr. Chairman, and members of the subcommittee for inviting me here today. It is certainly an honor for me to have the opportunity to testify before the U.S. Congress. And this issue on hand is very important to customers and consumers throughout America. Anyone who buys, cooks and eats chicken—and that is just everybody—has a stake in today's proceedings.

I don't know that much about politics, and I don't pretend to be an expert on the laws and the rules of the Department of Agriculture. Your other guests are certainly better able to address this subject. But I do know a few things about chicken.

I have been a chef for many years, and I love to cook. I think food does much more than just sustain us as human beings, because it enriches our daily lives and brings happiness to our families, and the right kind of food can, obviously, help keep us happy.

In terms of chicken, you are talking about one of my favorite foods to eat and to cook. There are so many different things you can do with chicken. You can eat it whole roasted, you can boil it, bake it, or serve it Chinese style, Japanese style, anyway you like it. Very few other types of food are this flexible. However, there is one thing you can't do with chicken. You can't freeze it as hard as a bone and still call it fresh.

Mr. Chairman, I didn't know you went shopping this morning. I certainly went and I am surprised they let us through the security check here because this is more like a weapon than a fresh chicken, as you can see.

I would certainly be aghast to tell my customers in our restaurants, and we have restaurants from high range to low range, to tell them we are serving fresh chicken, fresh roasted chicken or grilled chicken when they are really getting a product like that. And that is why I am here today.

I am told that the current government policy allows producers to label chicken fresh after it has been frozen solid, below 26 degrees Fahrenheit, or even as low as 1 degree.

I think in Europe it is a little bit easier, because we have zero, and zero there is a cutoff point. Everything below zero we call frozen. And here I don't know. The 32 degrees, I don't think is the answer.

One degree is about as frozen as you can get. The freezers in my restaurant, in fact the freezer compartment in a typical household refrigerator only gets down to about 20 degrees. In our restaurant we only freeze the ice cream. We don't need a freezer for chicken, because we serve it fresh.

But according to current fresh poultry standards, the frozen chicken in your freezer at home is considered fresh. So I don't go to many households to eat chicken anymore.

The truth is fresh chicken has never been frozen. Fresh chicken is moist and juicy while frozen is—or thawed out chicken—is very dry and tough. I cooked a few of those once too, and I certainly know the difference. That is because the process of freezing something removes the natural juices from poultry. Everybody knows

that when you freeze a chicken the juices come out and it makes it very dry, and also not as tasty.

In my opinion, fresh poultry is much better than frozen ones. It doesn't matter if it has been frozen to 1 degree or 25 degrees, frozen is frozen and fresh is fresh.

As I understand, some producers are trying to equate fresh and frozen chickens, but there is a huge difference. Fresh chicken is chicken that can be cooked and eaten right away. Frozen chicken, on the other hand, you have to thaw it out and then cook it.

And even though thawed out chicken can be eaten right away, that alone doesn't make it fresh. As I have said, a truly fresh chicken has not gone through the freezing and thawing process that make it much dryer and much tougher. That doesn't mean there shouldn't be frozen chickens around. I think there absolutely should be. It costs probably less, and if prepared well enough it still can fill up some stomachs.

But I think people deserve to know if poultry is truly fresh or whether it has been frozen once before by the producer. I think producers should have to disclose whether they have frozen something. They shouldn't mislead the customers.

Too freeze something and then thaw it out without telling people is not fair, and to label it fresh after it has been frozen is just unfair. It is wrong. Frozen or previously frozen food can never be fresh again.

We know that this is also true for many other foods we serve at the restaurants; that if it is fish or any vegetables they don't want to call it fresh.

That is another reason why this policy should be fixed. As most chefs will tell you it is not a good idea to freeze meat or poultry twice. When you refreeze and thaw out chicken a second time it will be even tougher. It wont last nearly as long as chicken that has been only frozen once. If you thaw chicken out a second time you must eat it right away. Twice frozen and twice thawed chicken will also allow bacteria to bloom much more than chilled chicken that has never been frozen or chicken that has been frozen only once.

The consumer who buys chicken in the fresh food section of the grocery store and who pays more for it than they pay for frozen chicken obviously assumes the poultry has never been frozen. That is what the fresh label is supposed to mean. And I really feel that my customers in restaurants have the right to know that we use fresh ingredients, and especially chicken, which is a part of our restaurant food service.

And since they don't know if it has been frozen already, they don't think there is a problem in bringing it home and putting it in the freezer. So if you freeze it twice it is obviously worse.

Everybody knows you should eat fresh chicken soon after purchase or you need to freeze it, but you shouldn't freeze it twice, and that is what happens today when a consumer unknowingly buys a falsely labeled chicken that has already been frozen.

I am mostly a businessman, and I can tell you that if my customers find out something on the menu which wasn't exactly what the menu said they would be out the door pretty quick. So far we

have been lucky, because I have very high standards and we only try to buy the freshest ingredients, the best ingredients possible.

Because we sell only fresh food at Spago and in our other restaurants and food that has never been frozen before, except ice cream. But you shouldn't have to eat at Spago or any other fine restaurants in Washington, New York or anywhere to know that the fresh chicken you are buying is really fresh. Consumers who want the best quality meat and poultry should be confident that the labeling is correct and honest, and I hope that we will get that.

Thank you very much.

Mr. TOWNS. Thank you very much.

Let me thank both of you for your testimony.

Let me begin by asking both of you this question. If I as a consumer go to a supermarket, is there anyway that I can tell whether the chicken or turkey in the case has been previously frozen between 26 and 0 degrees Fahrenheit and later defrosted and labeled fresh? Is there anyway I can tell?

Mr. PUCK. Well, I think the way it is right now it is very hard to tell. I think a real expert maybe would know about it.

But I think they should keep frozen chicken in the frozen food section and fresh in the fresh meat department or poultry department in the supermarket. That certainly would make it very easy for people to go and say I want to buy a frozen chicken. I go to this department for a fresh chicken, and go to that department for a frozen chicken.

Mr. VOSS. I would agree. I don't believe that there is anyway that a customer—a consumer can be assured that chicken is fresh with the use of fresh labels by those people who use chicken that was previously frozen.

Mr. TOWNS. Mr. Voss, let me raise this question with you. Has your department estimated the amount of consumer dollars spent in California on poultry labeled as fresh under USDA's regulations that was frozen between 26 and 20 degrees? What is the magnitude of the problem in California? Is there a difference in cost?

Mr. VOSS. We can get you that information, Mr. Chairman Towns. What we have done recently is that there is generally about a 50 cents spread per pound, the price that the consumer is willing to pay for fresh chicken versus frozen chicken. The actual tonnage of chicken today, I think you could ask that question better of the California poultry association later. I think they have the actual numbers.

Mr. TOWNS. Right. One other question to you. What is the extent of foodborne illness in California associated with poultry? And is there any data that compares the safety of fresh versus frozen poultry?

Mr. VOSS. There is no specific data that I know of. To my knowledge both frozen chicken and fresh chicken handled properly have no significant difference of health problems.

However, a frozen chicken can be stored longer and then rethawed. But once thawed, those two chickens are subject to the same biological forces and have the same opportunity to—of wholesomeness and also the same to be mistreated and have pathogens that can cause disease.

Mr. TOWNS. Just before I yield back my time, I would like to ask unanimous consent to include the testimony of Joanne Kozberg, who is the Secretary of State and Consumer Services Agency, into the record. She will not be testifying.

Without objection, so ordered.

[The prepared statement of Ms. Kozberg can be found in appendix 6.]

Mr. TOWNS. At this time I would like to yield to Mr. Condit.

Mr. CONDIT. Thank you, Mr. Chairman.

Once again let me thank Mr. Voss and Mr. Puck for being here. This is a very important issue to us and to California, and you have done a great service to this subcommittee by being here today.

Mr. Voss, I want to make sure we have this straight for the record. Is it your testimony that the California law was based upon the standard established by the USDA's policy memo 022B, which has been mentioned several times here today, then you were sued because you violated the poultry act clause that prevents State preemption?

Mr. VOSS. Correct.

Mr. CONDIT. Has your office been given any indication of when the USDA might be completing its reevaluation of the fresh label policy? Have you or your staffer been consulted in anyway in this process?

Mr. VOSS. I have not. To my knowledge, none of my staff has.

We have had—my State veterinarian has had one call from USDA alerting him to the fact that they are going to look at this issue. I recall a discussion with my veterinarian was what were the issues, what were the parameters that we saw or that he saw they ought to be looking at. That is, to my knowledge, the extent that we have had any communication at this point with USDA.

Mr. CONDIT. But there was not given any time line by which we would resolve this issue?

Mr. VOSS. No, sir.

Mr. CONDIT. Mr. Puck, given the confusion surrounding the labeling of poultry, how do you purchase chicken for your restaurants and know that it is fresh?

Mr. PUCK. Well, I think, obviously, we have to buy from local growers or local farmers who have fresh chickens. But I think one of the reasons I am here today is to make sure that these people don't try to sell me chickens of inferior quality for the price I am paying. And I think if we don't have very stringent labeling that fresh is fresh and frozen is frozen and a very straight line through it that is not gray I think it will be very hard for the consumer to know. And I really would be the first in line to say, "Listen. I want to know what it is." And I think it is very important.

I think that USDA has very weird rules. I remember I was here I think 2 to 5 years ago. They taught me how to make pizzas. They said pizzas cannot have tomato sauce. So, now I know that when a chicken is like that it is fresh.

So I don't know. I think they should have maybe one chef on the committee at the USDA. [Laughter.]

Mr. CONDIT. Mr. Puck, you raise an interesting point about freezing poultry produce twice. Could you please elaborate on the problem associated with this practice?

Mr. PUCK. Well, I think if you freeze it twice, you thaw it out, and bacteria grows. You freeze it again and you thaw it out again you are going to have even more bacteria. So that is really a very dangerous part.

And also I think when people don't know at home that it was frozen already once, so they are just going to put it in the freezer again, and when it comes out people are going to say, you know, there is something wrong with the chicken.

And even if you have no tastebuds at all you could really taste the difference. So I think they mislead the people right from the beginning and it is wrong.

Mr. CONDIT. Thank you very much.

Mr. Chairman, thank you very much, and I yield back the balance of my time.

Mr. TOWNS. Thank you very much, Congressman Condit.

Now I yield to Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

I have two areas I would like to ask about. One is on the poultry issue and the labeling of fresh that we have just been talking about.

Mr. Puck, you raised an issue in addition to the quality of meat, and that is the issue of consumer pricing. In other words, you say the consumers expect and normally do pay more for chickens that are labeled fresh. Is that your understanding?

Mr. PUCK. That is absolutely right. Yes.

Mr. SCHIFF. Is that true in your restaurants too? Do you pay more for——

Mr. PUCK. Well, I try to buy the best quality, and I believe the best quality is fresh. But the way it is now somebody could bring chicken from California, or from another State, wherever it comes from frozen and then just thaw it out and sell it as fresh to us. And I think it is really misleading.

Mr. SCHIFF. Let me be more specific, and let me, perhaps, turn to Mr. Voss on this question. What I am asking is in addition to being labeled fresh chicken, these chickens which have been—I am going to use the word frozen, that is what I would call them if you can go all the way down to zero degrees Fahrenheit—are they marketed in California and other places to your knowledge, Mr. Voss, at a premium price like a never frozen chicken would be marketed? Do you have knowledge of that?

Mr. VOSS. Yes, they are. They are marketed right alongside of a truly fresh chicken that has not been frozen——

Mr. SCHIFF. At the same price?

Mr. VOSS. Maybe not at the same price in that they may be a couple cents cheaper.

Mr. SCHIFF. But more than——

Mr. VOSS. But they are more than frozen chicken will be if it were frozen chicken in the store sold normally.

Mr. SCHIFF. Right. Well, that is what I am getting at. In addition to the consumer purchasing a product as fresh which was actually frozen, the consumer is paying more than the consumer would nor-

mally expect to pay for a chicken that has been frozen. Is that right?

Mr. VOSS. That is correct.

Mr. SCHIFF. The other issue I want to ask about to both of you gentlemen is, although we are here primarily to discuss poultry, I did ask the agriculture Department representatives about the labeling of beef as fresh, and they stated that—Mr. Rominger stated that the labeling of beef as fresh had nothing to do with whether it was froze on or not. That dealt with whether, I believe he said—I hope I am quoting him correctly. I believe he said it is a question of whether nitrates have been used with the meat.

I would like to ask you gentlemen is that your understanding of what fresh means in terms of fresh meat?

Mr. PUCK. Well, I think I learn everyday what fresh is. And I think I might come back here and some new things come out.

Mr. SCHIFF. Is this a new one on you?

Mr. PUCK. But I think—I didn't know about the beef. I really thought that, you know, if you buy fresh beef that it is fresh. We get beef from a farmer in Kentucky and I know it is fresh. But I think, because you cure beef then it is not fresh anymore, and if you freeze it, it is fresh, I don't think it makes sense.

Mr. SCHIFF. All right. So in your judgment, Mr. Puck, would either curing or freezing beef make it not fresh any longer?

Mr. PUCK. I would not call it that. If you cure it you have another product, basically. It is like from pork you make ham or from chicken you make smoked chicken or whatever, you know: but I think it is a different product and you should label it what it becomes, not just saying it is not fresh.

Mr. SCHIFF. Well, they would agree with you on the curing. But Agriculture Department says if beef is frozen that doesn't matter and it is still fresh: do you agree with that?

Mr. PUCK. No, I don't agree with them at all.

Mr. SCHIFF. Mr. Voss, what is your position on that?

Mr. VOSS. The same as Mr. Puck's. I think that the consumer deserves to know what they are buying. If it has been frozen it has been frozen.

Mr. SCHIFF. And it is not fresh anymore. It shouldn't have the fresh label.

Mr. VOSS. That is right. When we talk about frozen peas or frozen peaches or frozen strawberries, you can't label them fresh, because it is quite obvious when you thaw them out. Meat has a little different structure so it may not be so obvious to the untrained. But it is really no different than freezing vegetables.

Mr. SCHIFF. I thank both of you gentlemen. I yield back, Mr. Chairman.

Mr. TOWNS. Thank you very much.

At this time I yield to Congressman Payne.

Mr. PAYNE. Yes, Mr. Voss, I missed your testimony. But I wonder if the preemption—are there any other examples in California where a law is more stringent than what the Federal regulations are and has the government moved to preempt that area?

Mr. VOSS. We have several areas all of which are under challenge. Well, not all of them, but several of them that are under challenge even though we are more stringent or we require a high-

er health level, and the preemption is the issue. We have legal action against Food and Drug in the area of milk. We have other actions pending.

I think a serious concern that has to be looked at is the policy issue of putting out guidelines that really have no legal background: and we have had some experience in milk inspection where the California Department had enforced regulations upon producers for a number of years based on what people in the Department had thought were regulations at the Federal Government and when challenged in court a few years ago by the producer were found out that there was no standing. Our regulations were based not on a Federal regulation but only a policy recommendation, and obviously, we lost the case.

And I think that over many decades there have been a lot of these policy recommendations by USDA that were fine maybe 20 and 25 years ago, but in a legacious society that we live in today we are being challenged on when we find that we thought we were working on a historical legal basis and only find out they are recommendations.

Mr. PAYNE. We had hearings some years ago on the whole question of milk, and that is still a question, about the amount of antibiotic residues in milk and what should be consumed or not consumed.

What do you feel the consequences are of the breach in the labeling so far as the consumer is concerned? The fact that chicken is labeled as fresh and it is really frozen. Do you feel that this kind of action is going to serve as a detriment to the industry?

Mr. VOSS. No, I don't think it will in anyway serve to the long-term detriment of the industry. I think that the consuming public today obviously wants to know more about the food they buy, particularly in the area of food, the pesticides that have been applied, the nutritional value, the cholesterol—all of the issues that every one of us are much more conscious than we were a decade ago. And I think that those producers of those commodities that supply that information to the consumer will benefit in the long term if it is not mandated. And if it is mandated on the other hand, it still isn't going to hurt the industry because the consumer is looking for that.

Mr. PAYNE. With the new labeling and products, I think that there has been a tremendous amount of interest in the new type of labeling that FDA put in that gives the proper nutrients and the amount of fat and so forth, and it would seem that since the FDA were moving in that direction on labeling of products that are canned or packaged, it just seems to be out of step that FSIS would not be moving toward more truth in labeling as relates to the meat industry and the poultry industry.

Mr. Chairman, I have no further questions.

Mr. TOWNS. Thank you very much.

At this time I would yield to Congressman Mica.

Mr. MICA. Thank you, Mr. Chairman.

Let me see, Secretary Voss, you had stated in your written testimony in my view, this practice, speaking of the Federal labeling policy, is nothing less than an outright fraud, and the fact that it is sanctioned by the Federal Government is scandalous.

Could you elaborate on that? Do you really think the Department of Agriculture, is dealing in fraud and scandalous behavior.

I think it is in the context of what is expected from government and is expected by consumers today that it is fraudulent, an I think that it is scandalous if you were to look back in the context that in 1988 action was taken that would have rectified the problem that exists today and it still hasn't been put into practice. In fact, it has been withdrawn.

Mr. Voss, or secretary Voss, you heard the statement, or maybe you read the statement of Mr. Rominger, who is our Deputy Secretary of the Department of Agriculture. In his third paragraph he said in this administration USDA will not play a game of pins or Russian roulette with the lives of children, the elderly, the Nation, and the world's consumer. But aren't they, in fact, playing a poker game with the special interests and ignoring public health, safety, and welfare issues?

Mr. VOSS. I think that at this point in time I would say that. But I would say that I have been very supportive of Secretary Espy in the statements that he has made and what he has said he is going to do. The proof of the pudding is in the eating, of course, and we are not seeing much pudding yet.

Mr. MICA. We also heard the Secretary and the legal counsel say that originally they weren't going to enter the suit on the side of the Arkansas producers, but then they did. What kind of influence was exerted in your opinion to bring them into this suit?

Mr. VOSS. I have to assume that they came into the suit because Judge Levi asked them to do so. I do know that the industry interests, both those who were for it from California and those who are opposed to it had met with the secretary. And so I don't know that that had an impact one way or the other. But I do know that the judge did request that they come into it.

Mr. MICA. Aren't there, in fact, exceptions that are granted? For example, some kosher poultry products move outside some of these areas. In fact, I think that is in your statement.

Mr. VOSS. I am not sure that there is an exception, or whether it is just ignored. But kosher food laws in New York for one State are considerably different than what USDA has and there is no legal action been taken against them.

Mr. MICA. Chef Puck, thank you so much for coming. I just wanted to let you know that in addition to chefs liking chicken, people in public office, in order to stay in office, have to like chicken too. So we appreciate your comments here today, and also your interest in seeing that the health and safety of the consumer is well-served by labeling. Thank you.

Mr. PUCK. Thank you.

Mr. TOWNS. Mr. Peterson.

Mr. PETERSON. Thank you, Mr. Chairman.

Mr. Voss, I am sorry I missed your testimony. It is my understanding that apparently California like they do with a lot of things have—well, I wont characterize what it is. But that you apparently, if you are a retailer, you have different standards than if you are a wholesaler, in other words. You want to have these labels for things that are coming into your State on a wholesale basis, but you have some exemption in your law that allows retailers to basi-

cally have these frozen, what you call frozen chickens and they are exempt from this? Is this kind of like with dairy where I keep hearing these free market speeches from California and they sale more milk into CCC and they have a quota program which the rest of the country doesn't have? Is this a similar kind of deal that California has?

Mr. VOSS. As to your question about the exemption or the difference for the retailer, I am glad you asked that question. The legislature again on a bipartisan unanimous vote passed a new piece of legislation earlier this year that was signed into law by the Governor this morning, including retailers into same provisions basically that were here for the wholesalers.

Mr. PETERSON. So that situation that has existed will no longer exist?

Mr. VOSS. Correct.

Mr. PETERSON. So that is going to be applied to everybody. And that just happened this morning?

Mr. VOSS. It was signed this morning, yes. Rather appropriate for today.

Thank you. I appreciate your clarifying that for us.

Mr. TOWNS. Thank you very much.

At this time I yield to Congressman Horn.

Mr. HORN. Thank you very much, Mr. Chairman. And I appreciate the testimony of both witnesses. I notice in your colleague, secretary Kozberg's testimony, she makes the point that "the California law is about protection, not protectionism." I wonder if you could furnish for the record—I don't expect you to have it in your head—what is the amount of frozen chicken and fresh chicken produced in California and what is the amount of frozen chicken, fresh chicken produced outside of California. I know your agency is very good at statistics, and I suspect you have some sense of that, and I would just like it in the record at this point.

Mr. Mica mentioned a paragraph that I had showed him that you had omitted in your reading. The third to the last paragraph of your statement where you said we are very disappointed that USDA chose to enter the lawsuit against California. We note that several other States, including New York, have kosher laws that deviate from Federal standards, but USDA has not gone to court to challenge New York or other States with fresh laws similar to our own.

What I would like, Mr. Chairman, is a letter to go from us to the Department of Agriculture asking what other States have laws that deviate from their own, and what has the Department of Agriculture attempted to do about it.

So, if we could get that letter to Secretary Espy, Deputy Secretary Rominger, I would appreciate it.

That is all the questions I have.

Mr. CONDIT [presiding]. Thank you, Mr. Horn.

Mr. Barrett, do you have some questions?

Mr. BARRETT. Mr. Chairman, I have been in Congress for about 1½ years, and one of the things I find is that there are times when there are very complicated issues that are difficult to master, that take hours and hours of study. So, it is nice to come to a hearing where the issue is simply if it is fresh it is fresh, if it is frozen it

is frozen. I can't think of another issue that I have seen where the answer is more clearcut. And I will do whatever I can to work with you and other members to make sure that our labeling is done in such a way that when people buy fresh chicken, they are getting fresh chicken.

Thank you.

Mr. CONDIT. Thank you, Mr. Barrett.

Mr. Lucas, do you have any questions?

Mr. LUCAS. Thank you, Mr. Chairman. Just a couple. And I am not sure that the Secretary can answer and it may be more appropriate at a later point.

But just for curiosity's sake, as you heard me allude to earlier, being one of the pups? In so many processes up here, trying to get a better feel for what is going on, any idea just how many chickens are consumed in California in a year, in tons or however that is calculated? And that may be a question better directed to the——

Mr. VOSS. That would be a better question to the association, I think, later. I did read those numbers before I came, so I would know them and I forgot.

Mr. LUCAS. OK. And did I understand you to say earlier that there was something in the range of like a 50 cent difference between the price of fresh chicken, as a guesswork mate, between fresh chicken and frozen chicken on the shelf?

Mr. VOSS. That is what an industry survey showed when you looked at chicken as a whole in supermarkets across the State. That is there is about an average of 50 cents.

Mr. LUCAS. Thank you.

Yield back the balance of my time, Mr. Chairman.

Mr. CONDIT. Thank you, Mr. Lucas.

An that concludes the questions for this panel, and we do appreciate both of you being here very much. Thank you.

We will take panel three. Please come forward, remain standing and we will swear you in.

Please raise your right hand. Do you swear to tell the truth and nothing but the truth?

[A chorus of "I do."]

[Witnesses sworn.]

Mr. CONDIT. Let the record indicate they said I do.

We are going to start with Dr. Crawford.

Dr. CRAWFORD. Thank you, Mr. Chairman.

Mr. CONDIT. Do we have the names right now?

Dr. CRAWFORD. I believe so.

Mr. CONDIT. We are going to play musical chairs up here. We have a vote going on, so we are going to be in and out. Don't let that disturb you at all. You just keep up with your testimony and then we will all get back to where we were.

So, Dr. Crawford, you may proceed.

STATEMENT OF LESTER M. CRAWFORD, D.V.M., Ph.D., EXECUTIVE DIRECTOR, ASSOCIATION OF AMERICAN VETERINARY MEDICAL COLLEGES

Dr. CRAWFORD. Thank you very much. I will summarize my statement, Mr. Chairman, to the extent that it is possible.

The problem that we identified when I was associate administrator and later administrator of FSIS in the 1980's was that poultry could not be labeled frozen unless it reached the temperature of zero degrees Fahrenheit or below, while all poultry maintained at temperatures above zero were not allowed to be called anything other than fresh. That is to say FSIS had not identified an allowable term for poultry maintained at temperatures below zero degrees and biological freezing. Although water freezes at 32 degrees, biological tissues and fluids because of the presence of natural substances such as the electrolytes begin to freeze at lower temperatures.

In the case of poultry carcasses ice crystals begin to form at approximately 26 degrees. This signifies the onset of freezing. This temperature also signifies the point below which it is unreasonable to allow use of the term fresh. The presence of ice crystals and the appearance of a solid or semisolid state indicates semifrozen food, not fresh food. This is true whether it be poultry, beef, eggs, dairy products, fruits or vegetables. Similarly, the freezing temperature of water, 32 degrees is the point at which ice crystals begin to form, not the point of hard freezing, which is approximately 20 to 25 degrees. Refrigerators and refrigeration cases in grocery stores are kept at 41 to 43 degrees Fahrenheit. Home freezing compartments and supermarket frozen display cases are typically 20 degrees Fahrenheit or slightly lower.

FSIS believed in 1988 that it was necessary to define that area between poultry that was frozen—zero degrees or below—and fresh, no lower than 26 degrees. This decision was reached in the interest of providing a factual label. FSIS contemplated three categories of labels: fresh, fresh frozen or a similar term, and frozen. This determination was conveyed to FSIS and to the general public by means of policy memo 022B. Policy memos are informal documents intended to convey the thinking of the agency on various labeling issues. Other regulatory agencies use similar instruments to convey information. An example of this is FDA's use of "points to consider" documents. These documents, of course, do not have the force of law or regulation. They are used in subject areas that do not rise to the point of regulatory concern and at which the relevant statute appears to allow interpretation. These are generally not enforceable, and upon challenge are sometimes withdrawn or not enforced. In CNI v. Young, the courts held that informal action levels were extralegal. Policy memos, action levels, points to consider, and other subregulatory instruments can sometimes precede a regulation. Regulations take a long time and require enormous agency resources.

Policy memo 022B was appealing to some poultry producers and not appealing to others. After its issuance a series of meetings were held at USDA at the request of affected parties. Certain poultry producers stated that implementation of policy memo 022B would cause economic dislocation in the industry and that the public was satisfied with the current situation. Efforts were made at compromise, these were unavailing. No agreement could be reached either within FSIS or with the affected parties as to what the name of the new category might be. Fresh frozen was considered a contradiction in terms since such carcasses are neither fresh nor fro-

zen. Another potential term, "chill-pack" was found to violate a copyright. The suggestion of lowering the temperature at which poultry could be labeled fresh from 26 to 24 degrees was not acceptable to the agency.

Realizing that policy memo 022B was likely to be challenged, I personally examined some of the issues regarding that policy memo. Visits to local supermarkets revealed frozen poultry sections and fresh poultry sections which were clearly delineated.

Frozen poultry sold for less on a per pound basis than did fresh labeled poultry. Some poultry in the fresh poultry display case at which poultry was held at refrigeration temperatures above 32 degrees Fahrenheit was labeled neither fresh nor frozen, and it likewise sold for about 10 cents less than that labeled fresh.

During the late summer and early fall of 1988 I decided to embark on major programs to reform the food label and to research the causes of contamination of poultry. The first project developed into the USDA equivalent of the Nutrition Labeling and Education Act, the latter became the research underpinnings of the HACCP program.

I believed that many of our concerns about food labeling, including the so-called fresh issue, would be subsumed under the overall rubric of food label reform.

Similarly, I was confident that our knowledge of producing even safer poultry would be enhanced by the Puerto Rico study and the subsequent development of HACCP. It was for these reasons that I made the decision to cancel policy memo 022B rather than pursue the matter with notice and comment rulemaking. I had decided to pursue the matter we would have gone through the long and laborious process of effecting a regulation independent of overall food label reform. Although this process normally takes 2 to 4 years, I worked on one, Mr. Chairman, that took 24 years.

I am appending a couple of extra documents to the testimony, and with that in the record I conclude my opening statement at this point. Thank you very much.

Mr. CONDIT. Thank you, Dr. Crawford. And, without objection, your additional information will be included in the record.

[The prepared statement of Dr. Crawford follows:]

STATEMENT OF DR. LESTER CRAWFORD

EXECUTIVE DIRECTOR

AMERICAN ASSOCIATION OF VETERINARY MEDICAL COLLEGES

COMMITTEE ON GOVERNMENT OPERATIONS

SUBCOMMITTEES ON

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS

INFORMATION, JUSTICE, TRANSPORTATION AND AGRICULTURE

JUNE 16, 1994

STATEMENT OF LESTER M. CRAWFORD

I am Dr. Lester M. Crawford. I hold a degree in veterinary medicine and a Ph.D. in pharmacology and physiology. Early in my career, I worked in poultry inspection, private veterinary medical practice, and in pharmaceutical research and development. For 13 years I was on the faculty of the University of Georgia. Following 6 years at the U.S. Food and Drug Administration where I was Director of the Center for Veterinary Medicine, and after a brief stint at the World Health Organization I joined the Food Safety and Inspection Service (FSIS) in 1986 and served as Administrator from 1987 to 1991.

While serving as Associate Administrator of FSIS (1986-1987), we identified several food labelling issues that needed addressing. One of the most important was the labelling of fresh and frozen poultry. I tried to fully address this issue after I became Administrator.

The problem was that poultry could not be labelled "frozen" unless it reached a temperature of zero degrees Fahrenheit or below, while all poultry maintained at temperatures above zero were not allowed to be called anything other than fresh. That is to say, FSIS had not defined an allowable term for poultry maintained at temperatures between zero degrees and biological freezing. Although water freezes at 32 degrees, biological tissues and fluids, because of the presence of natural substances such as electrolytes, begin to freeze at lower temperatures. In the case of poultry carcasses, ice crystals begin to form at approximately 26 degrees. This signifies the onset of freezing. This temperature also signifies the point below which it is unreasonable to allow use of the term "fresh." The presence of ice crystals and the appearance of a solid or semi-solid state indicates semi-frozen food, not fresh food. This is true whether it be poultry, beef, eggs, dairy products, fruits, or vegetables. Similarly, the freezing temperature of water (32 degrees) is the point at which ice crystals begin to form, not the point of hard freezing (approximately 20-25 degrees). Refrigerators and refrigeration cases in grocery stores are kept at 41-43 degrees Fahrenheit. Home freezing compartments and supermarket frozen display cases are typically 20 degrees Fahrenheit or slightly lower.

FSIS believed in 1988 that it was necessary to define that area between poultry that was frozen (0 degrees or below) and fresh (no lower that 26 degrees). This decision was reached in the interest of providing a factual label. FSIS contemplated 3 categories of labels: fresh, fresh-frozen (or similar term); and frozen. This determination was conveyed to FSIS and to the general public by means of Policy Memo number 022b.

Policy memos are informal documents intended to convey the thinking of the Agency on various labelling issues. Other regulatory agencies use similar instruments to convey information. An example of this is FDA's use of "Points to Consider" documents. These documents of course do not have the force of law or regulation. They are used in subject areas that do not rise to the point of regulatory concern and in which the relevant statute appears to allow interpretation. These are generally not enforceable and, upon challenge, are sometimes withdrawn or not enforced. In CNI v. Young, the courts held that informal "action levels" were extralegal. Policy memos, action levels, points-to-consider and other sub-regulatory instruments can sometimes precede a regulation. Regulations take a long time and require enormous agency resources.

Policy memo 022b was appealing to some poultry producers and not appealing to others. After its issuance, a series of meetings were held at USDA at the request of affected parties. Certain poultry producers stated that implementation of Policy Memo 022b would cause economic dislocation in the industry and that the public was satisfied with the current situation. Efforts were made at compromise. These were unavailing. No agreement could be reached either within FSIS or with the affected parties as to what the name of the new category might be. "Fresh-frozen" was considered a contradiction in terms since such carcasses are neither fresh nor frozen. Another potential term, "chill-packed," was found to violate a copyright. The suggestion of lowering the temperature at which poultry could be labelled fresh from 26 to 24 degrees was not acceptable to the Agency.

Realizing that Policy Memo 022b was likely to be challenged, I personally examined some of the issues surrounding 022b. Visits to local supermarkets revealed frozen poultry sections and fresh poultry sections which were clearly delineated. Frozen poultry sold for less on a per pound basis than did fresh labelled poultry. Some poultry in the fresh poultry area at which poultry was held at refrigeration temperatures above 32 degrees Fahrenheit was labelled neither fresh nor frozen and it likewise sold for about 10 cents less than that labelled fresh.

During the late summer and early fall of 1988, I decided to embark on major programs to reform the food label and to research the causes of contamination in poultry in Puerto Rico. The first project developed into the USDA equivalent of the Nutrition Labelling and Education Act and the latter became the research underpinnings of the Hazard Analysis and Critical Control Point System (HAACP). I believed that many of our concerns about food labelling, including the so-called "fresh" issue, would be subsumed under the overall rubric of food label reform. Similarly, I was confident that our knowledge of producing even safer poultry would be enhanced by the Puerto Rico study and the subsequent development of HACCP.

It was for these reason that I made the decision to cancel

Policy Memo 022b rather than pursue the matter with notice and comment rulemaking. Had I decided to pursue the matter independent of food label reform, I would have first published an Advance Notice of Proposed Rulemaking (ANPR). Next I would have developed a proposed regulation based on the comments received on the ANPR. Finally, there would have been published a final rule based on comments from the proposed years. I worked with one rulemaking that took 24 years -- a veritable generation.

Mr. Chairman, I am appending to this testimony a statement that I provided to Federal Court in California on this matter that is relevant to the subject of your hearing here today. I also am providing an abstract of a paper I published in the journal Nutrition Reviews, which is pertinent to those portions of my testimony dealing with food labelling.

I would be pleased to answer questions. Thank you very much.

DECLARATION OF DR. LESTER CRAWFORD

I, Dr. Lester Crawford, declare as follows:

1. I am the Executive Director of the Association of American Veterinary Medical Colleges in Washington, D.C. I have personal knowledge of all of the facts stated in this declaration and, if called as a witness, could and would testify thereto under oath.

2. I received a Doctorate in Veterinary Medicine from Auburn University in 1963. I received a Doctorate in Pharmacology from the University of Georgia in 1969.

3. I was a Professor of Veterinary Medicine at the University of Georgia from 1966 to 1978 and from 1980 to 1982. At the University of Georgia, I headed up the Department of Physiology and Pharmacology.

4. I was the Director of the Center for Veterinary Medicine in the United States Food and Drug Administration ("FDA") from 1978 to 1980 and from 1982 to 1985. As Director of the Center for Veterinary Medicine in the FDA, I was the final authority with respect to veterinary drug approvals, animal feed regulation, animal device regulation, and animal drug regulation.

5. I was the Associate Administrator of the Food Safety and Inspection Service ("FSIS") of the United States Department of Agriculture ("USDA") from December, 1985 to September, 1987. I was the Administrator of the FSIS from October, 1987 to September, 1991. As Administrator of the FSIS, I was the highest official at the FSIS.

6. As Administrator of the FSIS, I reported to the Secretary of Agriculture. I was the final authority at the FSIS on all matters pertaining to federal inspection and labeling of meat and poultry. In my capacity as Administrator, I was responsible for approving or disapproving all plants that were eligible for production of both raw and processed meat and poultry, and products containing meat or poultry. Furthermore, I was responsible for the correct labeling of all meat, poultry, and products containing meat or poultry sold in the United States.

7. As Administrator of the FSIS, I oversaw the issuance of and reviewed all policy memos from October, 1987 to September, 1991. Under my administration, policy memos were used sparingly since they were designed only to reflect the developing thinking of the FSIS. Policy memos are not intended to state the permanent position of the FSIS. Rather, policy memos are meant to set out the current FSIS position.

8. In contrast, when the position of the FSIS is finalized, the position is stated in a regulation. The position of the FSIS is not legally enforceable until it becomes a regulation. Thus, if a party refuses to comply with a policy memo, the FSIS would have to relent because a policy memo is not legally enforceable. When the FSIS is ready to enforce a position in court, the FSIS states the position in a regulation.

9. Very few policy memos have resulted in the issuance of formal regulations. Indeed, when policy memos are challenged, they are often withdrawn or modified to meet the needs of the opposition.

10. Since policy memos are not final agency determinations nor do they have the force of law, policy memos are not intended to be preemptive of state law or any other law, or to be regulations or legal requirements. They are merely intended to give interested parties some insight into the current thinking of the FSIS. Policy memos are also considered to be useful in instructing those industries which are regulated and inspected by the FSIS.

11. During my tenure as Administrator, the FSIS issued two policy memos regarding the issue of labeling meat and poultry products as fresh. Policy Memo 022B, which is attached as Exhibit 1, was issued on July 11, 1988. Policy Memo 022C, which is attached as Exhibit 2, was issued on January 11, 1989.

12. In 1988, Perdue Farms, a major poultry producer, requested the FSIS to investigate the labeling of poultry as fresh. During our investigation, we found that a great deal of the poultry products that were labeled as fresh were clearly frozen. We believed that it was misleading and unfair to the consumer to label poultry as fresh when it was clearly frozen. Thus, we set out to develop a policy memo aimed at more accurate, informative, and fair labeling of meat and poultry products as fresh.

13. As a result of scientific research regarding the freezing of poultry, including a survey of the relevant scientific literature and studies conducted in FSIS laboratories, we concluded that 26 degrees Fahrenheit was the best dividing line between fresh and frozen poultry. This conclusion was based on our finding that ice crystal formation is present in the edible portions of the poultry carcass at and below 26 degrees Fahrenheit.

14. We memorialized our thinking on this issue in Policy Memo 022B. In Policy Memo 022B, the FSIS stated that "[a]ny poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core location)" could not be labeled as fresh. Exhibit 1, page 1, paragraph #3.

15. After the issuance of Policy Memo 022B, representatives of the poultry industry approached the Secretary of Agriculture Richard Lyng and me. Secretary Lyng and I had two meetings with certain members of the National Broiler Council ("NBC"), including Holly Farms and Marshall Durbin, who differed with the conclusions stated in Policy Memo 022B.

16. Secretary Lyng instructed me to meet with the members of the NBC to resolve the issue. Secretary Lyng told me to work with the NBC members and to develop an acceptable accomodation.

17. I met with certain members of the NBC. I was told that the vast majority of the NBC members wanted Policy Memo

022B abrogated. The NBC was unwilling to accept any compromise position. The NBC's position was that Policy Memo 022B be rescinded.

18. During the consideration of Policy Memos 022B and 022C, no consumers or state officials had input into these policy discussions.

19. Given the position of the NBC, I reluctantly rescinded Policy Memo 022B. On January 11, 1989, the FSIS issued Policy Memo 022C, which superseded Policy Memo 022B. In Policy Memo 022C, we stated that "[a]ny poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit" could not be labeled as fresh. Exhibit 2, page 1, paragraph #3.

20. I still believe that the conclusions stated in Policy Memo 022B were and are correct. I also continue to believe that it is misleading to label poultry that has been frozen to 26 degrees Fahrenheit or below as fresh because such poultry is clearly frozen. The change from 26 to zero degrees Fahrenheit was made as a political compromise.

21. Neither 022B nor 022C were intended to be preemptive of state law or any other law, or to be regulations or legal requirements. They were merely intended to set out the current thinking of the FSIS regarding the issue of labeling meat and poultry products as fresh.

22. Neither the USDA nor the FSIS has any current requirements mandating the labeling of poultry as fresh.

23. There are no laws or regulations on the books defining fresh poultry. The USDA has intentionally left a regulatory void in this area. Thus, the USDA has left it up to the states to define fresh poultry.

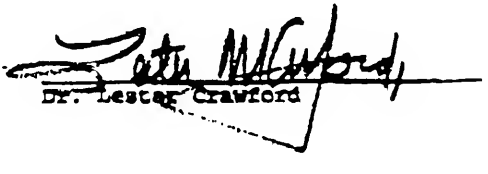
24. I have reviewed the California fresh poultry consumer protection law being challenged in this case, and believe it is a valid and worthwhile attempt to bring greater consumer protection into this area. I do not believe that the California law is preempted by any federal labeling requirement of the USDA that I am aware of.

25. I do not concur in the position that the USDA or the FSIS has total control over marketing and labeling of poultry, nor that the states are precluded from passing any laws regarding poultry labeling unless they are identical to federal regulations. I believe that the states are entitled to protect their consumers from misleading marketing and labeling of poultry when the USDA has not acted in the area.

26. I do not believe that the California law requires the addition of anything to poultry labeling. Nor do I believe that there is any current federal requirement that requires the affirmative labeling of poultry as fresh.

Executed this 24th day of February, 1994 at Washington, D.C.

I declare under penalty of perjury that the foregoing is true and correct.



Dr. Lester Crawford

The Food Label Reform Initiatives
The U.S. Departments of Agriculture and Health and Human Services

The current exercise in food label reform began in the summer of 1988 when agreement was reached between the United States Departments of Agriculture (USDA) and Health and Human Services (DHHS) to jointly undertake a complete overhaul of the food label. The stimulus for the effort came from the publication of the Surgeon General's report on Nutrition and Health.[1] Dr. Michael McGinnis, Deputy Assistant Secretary of Health, successfully brokered commitments from USDA and DHHS and has to a certain extent guided the considerable progress that has been made to date.*

The goals of food label reform as promulgated by the Congress[2] were to authenticate the label, to enhance the nutritional knowledge of the public, and thereby to improve the health and well-being of the American people. The current 90-day comment period (November 27, 1991–February 25, 1992) is in effect a national plebiscite on the practicality and the seriousness of food label reform. Both departments deserve commendation for their efforts thus far. Now it is up to the entire food and nutrition community to lay our prejudices aside and work together for a label that meets the best interests of all.

The proposals cover health claims, basic nutrition labeling rules, cholesterol, fat and percent fat-free labeling, serving sizes, Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs), voluntary nutritional labeling of raw fruits, vegetables, and fish, and nutritional descriptors. A brief look at significant changes is in order.

The new label would require listing total calories, fats, cholesterol, carbohydrates, protein, sugar, fiber, sodium, vitamins, calcium, and iron per serving for all processed products. Raw product labeling would be voluntary.

Serving sizes will be based on the reference amount normally consumed by an average person four years old or older. Servings per container will be expressed to the nearest whole number.

Total carbohydrates will be shown in terms of grams per serving, as will protein. Sodium will be listed in milligrams. Vitamins A and C will be listed as percentage of Daily Value** as will calcium and iron.

Claims made about certain ingredients trigger a requirement for quantitative testing. These include polyunsaturated and monounsaturated fats (in grams), sugar alcohols, soluble and insoluble fiber, protein (as percent of daily value), and vitamins and minerals not on the mandatory list.

Allowable listing is provided for the following nutrients: calories from saturated and unsaturated fat, total carbohydrates and protein, fat, sugar alcohols, insoluble and soluble fiber, potassium, thiamin, riboflavin, niacin, and other vitamins and minerals.

"Fat-free" products must contain less than 0.5 g fat per reference amount and per serving, and must not contain any ingredient that is a fat or oil. "__ percent fat-free" claims must meet the criteria for "low-fat" by containing less than 3 g fat per reference amount, per serving and per 100 g. The term "lean" will relate to meat or poultry products with less than 10.5 g fat, less than 3.5 g saturated fat, and less than 94.5 mg cholesterol per reference amount, per serving, and per 100 g. "Extra lean" will denote less than 4.9 g fat, less than 1.8 g saturated fat, and less than 94.5 mg cholesterol.

Significantly, "low-fat" labels will be allowed on products with standards of identity such as ice

*Credit should be given Dr. C. Everett Koop (Surgeon General 1981–89), USDA's Food Safety and Inspection Service (FSIS), the Food and Drug Administration (FDA), the National Academy of Sciences (NAS), and the U.S. Congress, for their roles in the process.

**Daily value includes the Recommended Daily Allowance (RDA) of vitamins and minerals and the Reference Daily Intake (RDI) of total fat, saturated fatty acids, unsaturated fatty acids, cholesterol, carbohydrates, fiber, sodium, and potassium.

cream, cheese, butter, and sour cream. Current regulations require the term "low-fat (butter) substitute"; now, it will read "low-fat butter."

Comments on the proposals will likely fall into the following categories:

1. The front-panel loading problem. Some will argue that "clutter" on the front panel will lessen the promotional value of the label and will render the more detailed information on the back panel uninteresting.
2. Label logistics. Reformatting the label may require large labels. It also will require new labels for every processed product on the market, and disposal of all label stocks at some point in time. There is a finite label production capacity in the United States, which may be exceeded.
3. Costs. It is widely felt that the government has underestimated the cost of label reform. Some believe the real cost will be sufficiently overwhelming to call into question the wisdom of label reform.
4. Effect on international trade. It is not clear from the proposals that sufficient emphasis has been given to the potential for trade disruption. Each country or group of countries, including the United States, has unique requirements for the labeling of imported products. Are we unwittingly blocking the flow of imported products or impeding U.S. exports with the proposals?
5. Prior approval of labels. Presently, FSIS preapproves all labels while the FDA does not. Some respondents are probably going to suggest that prior approval is not necessary; others are likely to suggest both agencies should employ the same procedures.

As one who has been involved in the food label initiative since its inception, I can only applaud the impressive array of talent, from within the government and without, who have worked so well and so diligently to create a food-labeling system that will materially improve the nutritional literacy and, ultimately, the health of all Americans. It is fervently to be hoped that public comment on the proposed regulations will be as constructive as it is thoughtful. The stakes are admittedly high but the opportunity for success is great.

Lester M. Crawford, D.V.M., Ph.D.
Executive Vice President—Scientific Affairs
National Food Processors Association
1401 New York Avenue North West
Washington, D.C. 20005

1. The Surgeon-General's Report on Nutrition and Health, 1988. Washington, D.C.: Department of Health and Human Services. Public Health Service, 1988. DHHS(PHS) publication no. 88-50210. Superintendent of Documents, U.S. Government Printing Office
2. Tillotson JE. United States Nutrition Labeling and Education Act of 1990. Nutr Rev 1990;49:273–6

Mr. CONDIT. I want to extend my apologies to the other two witnesses. I have just been informed we are going to have consecutive votes. That means we have got 5 minutes to get to this vote, and then we have a 5-minute vote after that.

So if we can stop here, maybe you can catch your breath or do whatever you need to do, and we will be back in just a few minutes. And I do apologize to you and appreciate your patience.

So we are going to recess at least 10 minutes.

[Recess taken.]

Mr. CONDIT. We apologize for the delay.

Ms. Golodner, we will begin with you, and we are sorry if we interrupted your momentum, but it was unavoidable.

STATEMENT OF LINDA F. GOLODNER, PRESIDENT, NATIONAL CONSUMERS LEAGUE

Ms. GOLODNER. Thank you.

Mr. Chairman and members of the subcommittees, my name is Linda Golodner. I am president of the National Consumers League, a national, private, nonprofit membership organization that represents consumers throughout the Nation. I am here today to testify on truth in labeling of poultry, an issue of paramount importance to consumers.

The current USDA rules which allow the sale of previously frozen poultry as fresh are a direct affront to providing consumers with accurate, truthful, and nonmisleading information. USDA's Food Safety and Inspection Service has determined that chicken freezes when it is chilled below 26 degrees Fahrenheit. At and below this temperature, ice crystals begin to form in the edible portions of the poultry carcass. Despite the scientific evidence, however, USDA policy allows poultry to be chilled as low as 1 degree Fahrenheit, shipped and then thawed and sold to consumers as fresh.

The National Consumers League has extensive experience working with the term "fresh" on the labeling of food products. NCL played an important role in FDA's action against Ragu Fresh Italian Pasta Sauce and Citrus Hill Fresh Choice Orange Juice labeling as false and misleading to consumers. In comments and letters to the FDA, NCL urged the agency to require the companies to stop misleading the public by making claims that the products were fresh when they were actually reconstituted or remanufactured from concentrate. NCL supported limiting the use of the term "fresh" on any fruit or vegetable product to products that are raw food that have not been frozen or subjected to any form of thermal processing or any other form of preservation.

NCL's efforts and FDA's action led to the companies' agreement to omit the word "fresh" from the label of these products. It was a major victory for consumers.

We are calling for similar action today. If consumers were misled by "fresh" on pasta sauce and orange juice, they are certainly misled by "fresh" on frozen chicken. The FDA definition clearly states that "fresh" is any food that has not been frozen, heat processed, or otherwise preserved. The FDA should not have one definition of "fresh" and the USDA another. Conflicting labeling rules are very confusing for consumers. The Random House dictionary defines

"fresh" as not frozen or canned, not preserved by pickling, salting, drying.

NCL did go to the supermarket and looked at other foods. At the fish counter, some fish are clearly marked "fresh," and other types of fish are labeled "previously frozen." Every consumer knows that there are frozen vegetables and fresh vegetables. We asked consumers would it be OK for someone to freeze a product and then sell that thawed product as fresh? The response is absolutely not. Since consumers pay anywhere from 40 cents to $2 a pound more for fresh poultry than for frozen, they deserve a guarantee that poultry labeled "fresh" is actually fresh, not previously frozen.

Mr. Chairman, as you are aware, the controversy surrounding this issue has been highlighted in the State of California. However, this issue spans beyond California, it is a national issue, and it concerns accurate, truthful, and nonmisleading information.

To put some integrity back into the labeling of poultry, we call upon the USDA to issue regulations establishing 26 degrees Fahrenheit as the standard for distinguishing fresh from frozen poultry. What is needed is a simple and clear rule that protects the interests of consumers and guarantees truth in labeling.

I was also asked to comment on USDA's progress in addressing microbial contamination of poultry products. We wish the progress were much faster. NCL, as part of the Safe Food Coalition, has urged USDA to improve the meat and poultry inspection system to help protect consumers from microbial contamination of meat and poultry. If we are going to spend time and money coming up with a better inspection system, let's make sure that it is better.

The test of the inspection program should be that finished meat and poultry products come off the end of the production line with such low amounts of bacteria that consuming the product is safe, that the product is clean, and that it won't make you sick. Base line studies on carcasses are valuable, but consumers do not buy carcasses. They go to the store and purchase a whole or a cut up chicken, ground beef, or preformed hamburger patties. Base line studies are needed on these highly processed end products.

In conclusion, the National Consumers League will continue to work with Congress and the USDA to ensure that truth in labeling and food safety are of primary interest, not the interest of regions, not the industry interest. We call on the USDA to issue regulations establishing 26 degrees Fahrenheit as the standard for distinguishing fresh from frozen poultry. Truthful labeling will enable consumers to make informed choices in the marketplace, and guarantee that the poultry that they buy for a premium price is truly fresh.

I would like to ask that a statement from Mark Epstein, executive director of Public Voice for Food and Health Policy, a sister consumer organization that has some comments on this issue, be made a part of the record.

Thank you.

Mr. TOWNS. Without objection, it will be included.

[The prepared statement of Ms. Golodner follows:]

National Consumers League
Founded 1899

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Testimony of

LINDA F. GOLODNER
PRESIDENT, NATIONAL CONSUMERS LEAGUE

Before the

Subcommittee on Human Resources and Intergovernmental Relations

and

Subcommittee on Information, Justice, Transportation and Agriculture

COMMITTEE ON GOVERNMENT OPERATIONS

UNITED STATES HOUSE OF REPRESENTATIVES

June 16, 1994

Representing Consumers for 95 Years

Testimony of
LINDA F. GOLODNER
PRESIDENT, NATIONAL CONSUMERS LEAGUE
Before the
Subcommittee on Human Resources and
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and
Subcommittee on Information, Justice,
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COMMITTEE ON GOVERNMENT OPERATIONS
UNITED STATES HOUSE OF REPRESENTATIVES
June 16, 1994

Chairman Towns, Chairman Condit, and members of the subcommittees, my name is Linda Golodner, President of the National Consumers League (NCL), a national, private, nonprofit membership organization representing consumers throughout the nation. Founded in 1899, NCL has represented consumers on safe food and labeling issues for 95 years. NCL supported passage of the Nutrition Labeling and Education Act of 1990 (NLEA) requiring nutrition labeling for most Food and Drug Administration (FDA) regulated packaged food products. The League also generally supports the Department of Agriculture's (USDA) efforts to regulate meat and poultry labeling, and today calls on the USDA to regulate the use of the term "fresh" on the labeling of poultry products. I am here today to testify on truth-in-labeling of poultry, an issue of paramount importance to consumers.

The National Consumers League firmly believes that an informed and educated consumer should be at the heart of the government's efforts to regulate the labeling of products. The current USDA rules which allow the sale of previously frozen poultry as "fresh" are a direct affront to providing consumers with accurate, truthful, and nonmisleading information. Consumers should be told the truth about what is often sold in supermarkets as "fresh" poultry.

USDA's Food Safety and Inspection Service (FSIS) has determined that chicken freezes when it is chilled below 26 degrees Fahrenheit (FSIS Policy Memo 022B, July 11, 1988). At and below this temperature, ice crystals begin to form in the edible portions of the poultry carcass. Despite this scientific evidence, however, USDA policy allows poultry to be chilled as low as one degree Fahrenheit, shipped, and then thawed and sold to consumers as "fresh" (FSIS Policy Memo 022C, Jan. 11, 1989). The current policy was adopted without consumer input.

The National Consumers League has extensive experience working with the term "fresh" on the labeling of food products. NCL played an important role in FDA's action against Ragu "Fresh Italian" pasta sauce and Citrus Hill "Fresh Choice" orange juice labeling as false and misleading to consumers. In comments and

letters to the FDA, NCL urged the agency to require the companies to stop misleading the public by making claims that the products were "fresh," when they were actually reconstituted or remanufactured from concentrate. NCL supported limiting the use of the term "fresh" on any fruit or vegetable product to products that are raw food that have not been frozen or subjected to any form of thermal processing or any other form of preservation. NCL was very concerned that consumers are misled by the use of the term "fresh" on products that have been processed. NCL also called on FDA to require that all foods containing reconstituted or remanufactured products display this fact prominently on the principal display panel. NCL's efforts and FDA's action led to the companies' agreement to omit the word "fresh" from the labeling of those products. It was a major victory for consumers.

We are calling for similar action today. If consumers were misled by "fresh" on pasta sauce and orange juice, they are certainly misled by "fresh" on frozen chicken. By specifically defining "fresh" in the regulations implementing the NLEA, FDA was able to safeguard fair and open competition in the food industry. This definition clearly states that fresh is:

> "Any food that has not been frozen, heat processed or otherwise preserved."

The FDA should not have one definition of "fresh" and the USDA another. Conflicting labeling rules are confusing. Consumers need reliable, truthful information about meat and poultry products. USDA should be consistent with FDA and the NLEA and issue regulations defining "fresh" as "any food that has not been frozen" below 26 degrees Fahrenheit. USDA's current policy which allows the labeling of previously frozen chickens as "fresh" is misleading.

As consumer representatives, NCL was puzzled at how any product that had previously been frozen could later be sold as "fresh." We thought perhaps we were missing something. Maybe the issue was more complicated. So, NCL checked some other sources to find out what fresh means to consumers.

The Random House Dictionary defines fresh as "not frozen or canned; not preserved by pickling, salting, drying...." NCL went to the supermarket and looked at other foods. We noticed the fish counter where some fish are clearly marked as "fresh" and other types of fish are labeled "previously frozen." There are frozen vegetables and fresh vegetables. We asked consumers if they thought, "Would it be O.K. for someone to freeze a product and then sell that thawed product as fresh?" The response was "absolutely not."

USDA's current labeling policy not only prevents consumers from knowing whether poultry labeled "fresh" has ever been frozen, but it also blocks consumers from making an informed choice between fresh and frozen poultry. They have no labels to compare at the supermarket. Poultry that is truly fresh is more tender and juicy and has a better texture than poultry that has been frozen below 26 degrees Fahrenheit. Since consumers pay anywhere from 40 cents to $2 a pound more for fresh poultry than for frozen, they deserve a guarantee that poultry labeled "fresh" is actually fresh, not previously frozen.

American consumers, increasingly concerned about nutrition and health, have been reducing fat in their diets by consuming more white meat, including chicken. If the poultry industry wants to take advantage of this growing market, it should be free to do so, but it should do so by providing accurate labels for consumers.

Chairman Condit, as you are aware, the controversy surrounding this issue has been highlighted in your home state of California. I commend you for using your leadership to bring this issue to the attention of Congress. However, this issue spans beyond California. It is national in scope, and it concerns accurate, truthful, and nonmisleading information.

To put some integrity back into the labeling of poultry, NCL calls upon the USDA to issue regulations establishing 26 degrees Fahrenheit as the standard for distinguishing fresh from frozen poultry. What is needed is a simple and clear rule that protects the interests of consumers and guarantees truth-in-labeling.

I was also asked to comment on USDA's progress in addressing microbial contamination of poultry products. NCL, as part of the Safe Food Coalition, has urged USDA to improve the meat and poultry inspection system to help protect consumers from microbial contamination of meat and poultry.

Since the E. coli 0157:H7 outbreak on the West Coast in January 1993, USDA has pledged to improve inspection and has taken some steps in that direction, most notably by considering mandating a Hazard Analysis and Critical Control Point (HACCP) system in meat and poultry plants. In addition, on March 9, Secretary Espy announced the "Enhancement Poultry Program," which would include a zero tolerance policy for fecal contamination of poultry. Zero tolerance for beef is already in place. We eagerly await specifics on USDA's poultry enhancement program and enforcement of zero tolerance for poultry.

The National Consumers League believes that mandatory HACCP holds great promise of improving the safety of meat and poultry products. However, we believe that USDA's HACCP program should:

1) Require that plants using HACCP sample for pathogenic bacteria both at critical control points and at the end of the production line to verify that the HACCP program is working as intended; and

2) Establish maximum acceptable levels of pathogenic bacteria for raw meat and poultry products. The HACCP program in each plant must be capable of regularly producing product that falls below these maximum levels.

If we are going to spend all this time and money coming up with a new inspection system, let's make sure that system is better. Let's make sure it's cleaner, safer, and less likely to make people sick.

Assistant Secretary Jensen recently told the House Agriculture Committee that the Department is working to reduce bacterial contamination. The Department is:

- Conducting a number of baseline studies to measure the amount of contamination on beef and hog carcasses at slaughter.
- Working to determine the level of bacterial contamination in live animals.
- Conducting a number of studies of rinses and dips and sprays that will kill bacteria.
- Beginning to look for rapid tests that are capable of detecting bacterial contamination on a production line.

These studies are not without value. However, the objective of meat and poultry inspection should be to prevent people from getting sick. Therefore, the test of whether an inspection program will meet that goal is to determine whether finished meat and poultry products come off the end of the production line with such low amounts of bacteria that consuming the products is unlikely to make a person ill.

Baseline studies on carcasses are valuable, but consumers do not buy carcasses. They go to the store and purchase a whole or cut-up chicken parts, ground beef, or preformed hamburger patties. Baseline studies are needed on these highly processed end products.

NCL is encouraged by recent action by the House Appropriations Committee setting aside $5,756,000 to further enhance USDA's Pathogen Reduction Program. With this targeted funding, FSIS is directed "to develop and establish a microbiological criteria by which safety and wholesomeness of food can be assessed, and to develop procedures to effectively

review for microbial contamination." Furthermore, the Appropriations Committee expects USDA's HACCP program to include microbial pathogen sampling at critical control points, along with end-product testing to verify that the HACCP system is working as intended.

In conclusion, the National Consumers League will continue to work with Congress and the USDA to assure that truth-in-labeling and food safety are of primary interest -- not the interests of regions or industry. NCL reiterates its call to USDA to issue regulations establishing 26 degrees Fahrenheit as the standard for distinguishing fresh from frozen poultry. Truthful labeling will enable consumers to make informed choices in the marketplace, and guarantee that the poultry they buy at a premium price is truly fresh, not previously frozen.

Thank you for the opportunity to testify today.

[The prepared statement of Mr. Epstein can be found in appendix 6.]

Mr. TOWNS. At this time, Mr. Leonard.

STATEMENT OF RODNEY E. LEONARD, EXECUTIVE DIRECTOR, COMMUNITY NUTRITION INSTITUTE

Mr. LEONARD. Thank you, Mr. Chairman.

Dr. Crawford in his opening statement referred to CNI's long-term interest in Federal labeling and food safety policy. We won a lawsuit several years ago to force the Commissioner of the Food and Drug Administration to follow the law. The result of that—he didn't conclude what really happened out of that—we won the lawsuit, but then the Commissioner of the Food and Drug Administration told us, in effect, that we now could go to try to enforce it. We have been fighting these battles for a very long time.

The fresh poultry labeling policy represents another example of triumph of politics over science. It is a win for the large poultry processors over the rights of American consumers. It is an absurd policy with no scientific justification, and it renders the distinction between fresh and frozen products meaningless.

This has not always been this way. For a long time we really didn't have this problem when I was the administrator of the agency but only began to develop as a problem in the late 1970's and the 1980's and, as has been recounted here, in 1988 and 1989 the Department defied all logic, reduced the temperature of fresh to zero degrees Fahrenheit, and, quite simply, the decision was ordered by the Secretary's Office without any justification, or any scientific justification.

The 26 degree definition makes sense because it is the lowest point at which ice crystals do not form in the muscle tissue of the poultry. Once ice crystals begin to form, cell damage occurs; the other physical characteristics of frozen product—that, is taste, smell, and texture—become noticeable.

It is always interesting trying to figure out how you explain Federal policy to most Americans, and in this case I think they would describe the current policy as: When is a frozen chicken a fresh chicken? Whenever it is regulated by the Department of Agriculture.

The current policy legalizes economic adulteration by allowing dishonest claims about the nature of the product to be passed along to consumers. It makes a mockery of the recent proclamation that the Department supports honest nutrition and food safety labeling, and it also has some economic impact that it promotes increased monopolization in an already highly concentrated industry.

Serious as these issues are, I think they are merely symptomatic of deeper problems within the Department. The Secretary of Agriculture is under investigation for accepting trips and housing, as the guest of Tyson's Food, the country's largest poultry processor, the world's largest poultry processor. The acting secretary in charge of meat and poultry inspection acknowledges accepting transportation and a seat in a Tyson box at a basketball game. Both Mr. Espy and Ms. Jensen say they repaid Tyson for all the expenses, but that is not the point. The law says that public officials responsible for food safety cannot accept such gifts regardless

if the beneficiary repays the benefactor, for a very simple reason, credibility. Once established, a beneficiary relationship destroys the credibility of any claim that the program is operating in the public interest.

Inspectors on the line in poultry plants and red meat plants are prohibited from accepting gifts because of the concern in the law for ethics and credibility.

Thus, it comes as no surprise to an incredulous public that the Department is now considering a poultry inspection plan that would cut back on the number of Federal inspectors, increase line speeds, and hand over key public safety responsibilities to employees of poultry processing plants. If this process is approved, it will pave the way for a public health disaster greater even than the E. coli outbreak 18 months ago.

This close relationship is why we need an independent Federal food safety agency. It is a conclusion I have reluctantly reached even though I once headed the inspection programs. An independent agency has received the backing of the General Accounting Office, and it had the support of the Vice President's Reinventing Government food safety task force. The Vice President, however, decided against creating another government bureaucracy.

But it is clear that regardless of the political bent of whatever administration is in the White House, no political leader in the Department of Agriculture can resist the blandishments of an industry it supposedly regulates. The failure of the Clinton administration to act upon a gross dereliction of its managers in USDA simply underscores the fact that the White House does not yet understand the depths of this problem.

An independent agency will free policy from the dictates of a few politicians in the Department and allow food safety to be based on science, and unless Congress addresses structural questions within the Department it will continue to hold hearings on absurdities like this for a very long time.

Thank you.

[The prepared statement of Mr. Leonard follows:]

CNI
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Testimony of Rodney E. Leonard, Executive Director,
Community Nutrition Institute
before
The Human Resources and Intergovernmental Subcommittee and
Information, Justice, Transportation, and Agriculture Subcommittee,
of the Committee on Government Operations.

June 16, 1994

"When is a frozen chicken a fresh chicken? When it's regulated by the Department of Agriculture."

Chairmen, Members of the Subcommittee, thank you for inviting me here today to discuss the Department of Agriculture's policy on fresh and frozen labeling of poultry. I am Rodney E. Leonard, executive director of the Community Nutrition Institute, a consumer advocacy organization I founded in 1969 after serving as the Administrator of the USDA's Consumer and Marketing Service.

The USDA's fresh poultry labeling policy represents the triumph of politics over science, and a win for large poultry processors over the rights of American consumers. It is an absurd policy with no scientific justification that renders the distinction between fresh and frozen products meaningless.

Until the late 1980's, "fresh" poultry was defined as having a between 26 and 32 degrees Fahrenheit. Until that time, this wasn't an issue — frozen chicken was properly termed frozen chicken. In 1988, bowing to industry pressure, the Department defied all logic, reducing that temperature to zero degrees Fahrenheit. The decision was ordered by the Secretary's office, without any scientific justification.

I'm reminded of TV ads run by Frank Perdue, in which he used one of his competitor's allegedly "fresh" chickens — under the zero degree guideline — to hammer a nail through a board. The ad succeeded because no one outside a few narrow interests could define a chicken with the consistency of a brick as fresh.

The 26-degree definition makes sense — water held by poultry carcasses contains salt and organic compounds that lower the temperature at which the water will freeze. At 26 degrees, no ice crystals form in the muscles of the bird, so the cells are not disrupted. But at zero degrees, ice crystals *do*

(more)

form, damaging cells, and lending the meat its characteristic frozen taste, smell, and texture. At that temperature, the meat is frozen; try explaining the policy to most Americans, and they'll respond with a crack about government ineptitude. When is a frozen chicken a fresh chicken? When it's regulated by the Department of Agriculture.

The 26 degrees definition also makes sense from a public health standpoint. Bacterial growth and enzymatic action slow between 32 and 26 degrees, preventing the spoiling of the meat. But since ice crystals won't form above 26 degrees, processors can legitimately sell their product as fresh.

The current policy legalizes economic adulteration by allowing dishonest claims about the nature of the product to be passed along to consumers. It makes a mockery of the USDA's recent proclamations that it supports honest nutrition and food safety labeling. And it promotes the increasing monopolization of the poultry industry, by allowing companies to ship frozen birds across the U.S. and then claim the meat is fresh.

Serious as these issues are, they are merely symptomatic of deeper problems within the U.S. Department of Agriculture. The Secretary of Agriculture is under investigation for accepting trips and housing as a guest of Tyson Foods, the largest U.S. poultry processor. These included visits to Arkansas and to Los Angeles to attend the Oscar ceremonies. The Acting Assistant Secretary in charge of meat and poultry inspection acknowledges accepting transportation and a seat in the Tyson box at a basketball game. Both Mr. Espy and Ms. Jensen say they repaid Tyson for all expenses, but that is not the point. The law says public officials responsible for food safety cannot accept such gifts, regardless if the beneficiary repays the benefactor, for a simple reason: credibility. Once established, a beneficiary relationship destroys the credibility of any claims that the program is operating in the public interest.

Thus, it comes as no surprise to an incredulous public that the Department is considering a poultry inspection plan that would cut back on the number of federal inspectors, increase line speeds, and hand over key public safety responsibilities to employees of poultry processing firms. If approved, this policy would pave the way for a public health disaster greater even than the *E. coli* outbreak 18 months ago.

This close relationship is why we need an independent federal food safety agency — a conclusion I have reached even though I once headed the USDA's inspection program. An independent agency has received backing from the General Accounting Office, and had the support of the Vice President's "Reinventing Government" food safety task force. The Vice President, however, decided against creating a new "government bureaucracy." It is clear that regardless of the political bent of whichever administration is in the White House, no political leader of USDA can resist the blandishments of the industry it supposedly regulates. The failure of the Clinton administration to act upon the gross dereliction of its managers in the USDA simply underscores the fact that the White House does not understand the depth of the problem.

But an independent agency will free policy from the dictates of a few politicians in the Department, and allow food safety policy to be based on science. Unless Congress addresses structural questions within the USDA, it will be holding hearings on absurdities like this one for a very long time.

Again, thank you for the opportunity to discuss these matters with you. I look forward to answering any questions you might have.

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Mr. TOWNS. Thank you very much for your testimony, all of you.

Let me begin with you, Dr. Crawford. Your statement mentions that as part of policy memo 022B, in 1988 USDA conducted an investigation of poultry labeled as fresh. Did you believe then and do you believe now that you had sufficient scientific data to determine the temperature at which poultry becomes frozen?

Dr. CRAWFORD. Yes.

Mr. TOWNS. Did USDA rescind the policy memo 022B because of pressure from certain segments of the poultry industry?

Dr. CRAWFORD. Well, I was instructed to try and work out an accommodation so that basically everybody would be happy. I couldn't do that partly because we couldn't come up with innovative approaches, and, second, because segments of the industry I think conscientiously believed it would cause economic hardships for the industry.

Failing to do that, what I decided do was to put it under the overall rubric of food label reform and hope to get to that as well as some other inequities in that way, Mr. Chairman.

Mr. TOWNS. Your declaration states the change from 26 to zero degrees Fahrenheit was made as a result of a political compromise. Does this mean that the change was not made for scientific reasons?

Dr. CRAWFORD. There were no scientific issues at issue, really, that I am aware of. The only issue was whether or not this could be accommodated in a way that would be appealing to both sides of the argument in the industry. I was told to work it out in a harmonious way. I could not, and that can only be described as not a scientific compromise but a political compromise.

Mr. TOWNS. Let me ask you, when you were trying to work it out, did you meet with any consumer groups?

Dr. CRAWFORD. I did not meet with any consumer groups, no.

Mr. TOWNS. Well, let me move on. I think you get the point.

Ms. Golodner—is that right?

Ms. GOLODNER. Golodner.

Mr. TOWNS. Golodner. Let me ask you a question that I asked the earlier panel, and you were probably here for that. If I as a consumer go to a supermarket, is there any way that I can tell whether the chicken or turkey in the case has been previously chilled between 26 and zero degrees Fahrenheit and later defrosted and labeled as fresh?

Ms. GOLODNER. There is no way you can tell, and I think the consumers are being misled because they think that if they buy a fresh chicken it is fresh. I think experts might be able to tell by looking at the chicken if it has been frozen, but certainly an average consumer can't tell.

Mr. TOWNS. So for lack of a better term, a lot of people are just getting ripped off.

Ms. GOLODNER. Absolutely.

Mr. TOWNS. Is there any scientific rationale for having two definitions of fresh, one for foods regulated by the Food and Drug Administration and one for meat and poultry regulated by USDA? Is there any reason for that?

Ms. GOLODNER. No. All we ask is that the food is safe, and if it takes freezing the food to make it safe, fine, but please label it as

frozen. If you are going to buy fresh products, you want them fresh and not previously frozen. They taste different.

Mr. TOWNS. This committee has been reviewing the Vice President's recommendation to reinvent Federal food safety. In fact, Mr. Leonard talked about it a little bit there. Some believe that the Department of Agriculture's mission to promote agriculture overshadows its responsibility to protect consumers. Do you think there is a structural conflict of interest inherent in the Department of Agriculture?

Ms. GOLODNER. I think that there should be studies into the way that the Federal Government is approaching food safety. I know Mr. Leonard testified on having a separate food agency, and I think that that should be considered. I agree, it appears that there could be a conflict of interest within the Department of Agriculture right now.

Mr. TOWNS. Dr. Crawford, I would like to hear you on that, too.

Dr. CRAWFORD. To the same questions, Mr. Chairman?

Mr. TOWNS. Yes, same question.

Dr. CRAWFORD. Well, I think that in terms of the inherent conflict issue, it is true, as I believe the Deputy Secretary said, that the food safety aspects that are under USDA's purview are in a different agency, and I don't—I don't think that that is something that cannot be managed just because it is in USDA, in my experience. However, I do think that it would make more sense to get all food safety in the Federal Government in the same agency or same Department, and I testified before you before in that regard.

Mr. TOWNS. Fine.

Mr. Leonard, I would like to ask you, why do you believe that we should remove meat and poultry regulation from the Department of Agriculture?

Mr. LEONARD. I feel we ought to put all food safety responsibilities in a single agency. I think we have seen it is impossible for the current arrangement at the Department to continue to function. I would disagree with Mr. Rominger in that the Department from 1907 until probably around 1980 or 1970 or 1975 probably could have done that. But once you begin getting the highly concentrated aspects of both poultry and red meat, I mean here you have got poultry, you have got basically four companies that control the market on red meat, you have probably three or four companies that dominate the industry. It is very difficult unless you can find some way of removing the regulatory aspects from the political pressures that come about with that kind of power. There is no assurance that creating a an independent agency will solve that problem.

If you look at the history of regulatory programs in the United States starting around 1870, what you see is about a 20 to 30-year cycle in which a regulatory policy is adopted. It continues, it gradually becomes corrupted; Congress comes back to it, creates a new structure; that exists for another 25 or 30 years. If you go back, the last time Congress really looked seriously at these issues was in 1967 and 1968. Actually, it was 1958 through 1967. They created the mandated poultry inspection in 1958 along with the Delaney clause.

The reforms in meat and poultry inspection were enacted in 1967 and 1968. That is the last time any—it is the last time Congress has seriously looked at this history. So we are now getting to be the 20 and 30-year cycle, and it is time again to look at it and put a new structure together.

Mr. TOWNS. Thank you very much. My time has expired. I yield to Congressman Condit.

Mr. CONDIT. Ms. Golodner, you stated that poultry that is fresh, nonfrozen, costs up to $2 a pound more than poultry that has been frozen. How can the consumer be sure that the product being purchased even at the higher price is truly fresh?

Ms. GOLODNER. You obviously can't, because if it is not labeled as either fresh or frozen a consumer can't tell the difference. However, some experts could tell by the looks of a chicken whether or not it has been frozen. You certainly find out when you eat it.

Mr. CONDIT. So you have to be an expert almost to determine if a chicken has been previously frozen.

Mr. Leonard, in your experience at the USDA, Consumers and Marketing Service administrator, were you ever frustrated that the industry concerns took precedence over those of the consumer?

Mr. LEONARD. Yes, it was a constant problem. I was fortunate in being able to have the support of a strong Secretary, Orville Freeman, and he backed me up on how I dealt with these issues, so we were able, for example, to merge meat and poultry inspection. They were separate agencies at the time, and we were able to demonstrate to the Congress that we could do this and save about $4 or $5 million a year in administrative costs.

He backed us up on making the changes in both meat and poultry inspection so that we were able to bring legislation to the Hill, and Congress responded by passing the legislation in 1967 and 1968. But we were always faced with that.

You know, as an administrator you are always faced with those kinds of pressures. Dr. Crawford gave you one inkling in a very polite way of those kind of pressures. You need to have people tell you, however; don't try to work it out; you need to ask, "What do you think ought to be done?", and then say, "OK, you go do it and I'll support you."

Mr. CONDIT. Thank you.

Dr. Crawford, in a meeting with your staff, you described efforts to reach a compromise with the industry representatives in defining "fresh." You stated that you rejected an industry proposal to define "fresh" as above 24 degrees, yet we ended up with a standard set at zero. How did we get from 26, 24, to zero?

Dr. CRAWFORD. The 26 is what we considered to be the point of biological freezing. Water is 32; chicken carcasses are 26; 24 would not have been acceptable scientifically or from a regulatory point of view because it couldn't be enforced because it is too low, and what we did was, rather than define it at the wrong figure, we didn't define it at all.

Mr. CONDIT. So you gave up?

Dr. CRAWFORD. We put it into the overall aspect of food label reform, hoping to get at it through either congressional intervention or the overall changing of the food label, and I think they may still do that, but I am not sure.

Mr. CONDIT. So can I say that you didn't find any middle ground anywhere so you just walked away from it?

Dr. CRAWFORD. Didn't really walk away from it. I had two choices. I could have gone the regulatory route—that is, published an advanced notice of proposed rulemaking—or put it in with all the other food label reform issues, and that is what I did do.

Mr. CONDIT. Dr. Crawford, you stated that the FSIS opted to write a policy memo on fresh labeling because regulations take a long time. Well, this one has taken about 6 years. In hindsight, would it have made more sense for the USDA to issue a regulation on this issue, and should we do so today?

Dr. CRAWFORD. Well, we had just done one on another labeling problem which was called the flavorings problem, and that is where we required that if you add something like MSG to meat or poultry, you have to declare that rather than flavorings, and that was done in only 3 years. So in retrospect perhaps that would have been the way to go.

Mr. CONDIT. Ms. Golodner, has the National Consumer League ever contemplated any legal action against the USDA because of the fresh labeling policy, and could you describe the group's past efforts in working with the pasta sauce that you mentioned and orange juice labels.

Ms. GOLODNER. To your first question, no we haven't considered legal action against the USDA. When we approached the Food and Drug Administration with regard to pasta and Citrus Hill orange juice, we wrote a letter to the Commissioner—wrote several letters to the Commissioner and let him know our views and what consumers felt was fresh and not fresh. Then the Commissioner did act on that policy and pulled the Citrus Hill, if you remember, from the shelves.

Mr. CONDIT. Dr. Crawford and Mr. Leonard, my time is almost up so maybe we could do this quickly. As a former—as former USDA officials, I am sure you have a strong feeling about how the Department should conduct its rules and policymaking. Could you briefly describe how you would go about conducting the fresh label review that Secretary Espy ordered this year? If you could do it quickly, I would appreciate it. If not, you can submit it to me in writing.

Dr. CRAWFORD. Yes. The way I would do it is, I would—I would make a proposal. I understand they are coming out with food label reform announcements in September. I believe that will be in the form of a proposed regulation, and I think they should include this there for public comment.

Mr. LEONARD. I think the scientific evidence is so clearcut that you don't have to go through all this pushing and filling. Issue a regulation defining "fresh" and defining "frozen." Give industry 30 days or 60 days to comment on it, give the public comment time, and unless there is some overwhelming scientific reason that isn't evident, then you go ahead and issue the regulation. You don't have to wait.

Mr. CONDIT. Thank you very much, Mr. Chairman.

Mr. TOWNS. Thank you very much, Congressman Condit.

At this time I yield to Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

Gentlemen, I assume you have seen the publicity around allegations naming the present Secretary of Agriculture and perhaps other members of the Agriculture Department as directly or having the appearance of impropriety in accepting certain things from—personal gratuities from part of the poultry industry.

I am not going to get into that at this particular time, you may have heard the reason for that at the beginning of the hearing. But I would like to ask you this. The present Deputy Secretary, Mr. Rominger, has stated that as a policy it was understood that there had to be both—there had to be an arm's distance between regulators and the industries that are regulated, which was an appropriate answer.

What I would like to ask is, the two of you served in the Department of Agriculture in different time periods. Are you aware of any undue personal contacts, gratuities and so forth, between high officials at the Department of Agriculture and the poultry industry, or I'll make it meat—I'll broaden that to include other forms of meat.

Dr. CRAWFORD. Are you talking about during my time in office?

Mr. SCHIFF. Right.

Dr. CRAWFORD. No, I am not.

Mr. SCHIFF. All right.

Mr. Leonard.

Mr. LEONARD. Not meat and poultry. We had problems outside of that with officials taking emoluments which were improper. In those cases, we dismissed them immediately.

Mr. SCHIFF. OK. Thank you very much, both of you.

Dr. Crawford in particular, I would like to go back to these memos, 022B and 022C. If I understand correctly—first, both of those memos were issued by you in your tenure as head of FSIS. Is that right?

Dr. CRAWFORD. Yes.

Mr. SCHIFF. Prior to 022B, was there any policy statement or other initiative from the Department of Agriculture that attempted in any way to define the difference between fresh and frozen with respect to poultry?

Dr. CRAWFORD. No. During my time there, that was undefined.

Mr. SCHIFF. All right. So you sort of made a stab at trying to get that done through those memos.

Dr. CRAWFORD. Yes.

Mr. SCHIFF. And 22B—just to make sure this is clear, was the proposal that 26 degrees was the margin for calling something no longer fresh if it was chilled below that, right?

Dr. CRAWFORD. Yes.

Mr. SCHIFF. All right. And then if I understand—I am trying to move this along, but please correct me. If I understand correctly, you issued 22C at zero degrees Fahrenheit basically just to move the whole approach to some other forum. That is really what you were trying to do.

Dr. CRAWFORD. Yes.

Mr. SCHIFF. Rather than adopt the 24 degrees, for example, which you felt was not scientifically based.

Dr. CRAWFORD. Yes.

Mr. SCHIFF. But why issue any memorandum? In other words, if you believed that the memorandum 022B was accurate, 26 degrees

was the appropriate line, and you felt that, for whatever reason, you didn't want to issue 22B or continue to issue—abrogate it, why substitute something which is still inaccurate?

Dr. CRAWFORD. You have—you have to put yourself in my place, which may be difficult, but the point is that we had hundreds of thousands of labels already out there. Those would have had to be called in, every one of them, and changed. Now we would have had to have rescinded all those labels retroactively.

Mr. SCHIFF. Excuse me, sir. If you had done nothing, if you didn't have any——

Dr. CRAWFORD. If we hadn't done 022C, you see, because we—in other words, what 022B said was that this is the informal thinking of the agency and we are going to go forward with this, so we would have had to address the matter of the labels.

It is possible that legally, since the policy memos are so weak as legal tools, that we might have had to grandfather the previous labels; but on new labels coming in, we would have had to enforce it. That is almost an untenable situation. We might have been able to proceed, as you say, had there not been a challenge, but I had every reason to believe that we would have had a legal challenge.

Mr. SCHIFF. But if you had abrogated 022B, 26 degrees, and not put anything in its place, then there would be no policy statement. So how would that have adversely affected whatever labels were out there?

Dr. CRAWFORD. Well, 022B did—you know, did basically say that you may not call something fresh if it has ever been below 26 degrees.

Mr. SCHIFF. I understand, and if you abrogated 022B without putting in 022C, how would that have been bad?

Dr. CRAWFORD. Well, 022C did abrogate 022B. It was the instrument to do that.

Mr. SCHIFF. But it also put in the zero degree definition for—still for fresh chicken, right?

Dr. CRAWFORD. The zero degree was already there before 022B. So basically what 022C did was, take it back to ground zero.

Mr. SCHIFF. All right. Where did the zero degrees come from, because when I asked you earlier——

Dr. CRAWFORD. The zero degrees came from the mists of antiquity. I don't know where that came from.

Mr. SCHIFF. OK. Thank you. Thank you.

All right. That answers my question.

Well, let me take it a step further. You say the policy—these are policy memos, and you have described them both in your written statement and just now in oral testimony as being relatively weak methods of enforcement because they are not only not statutes, they are not even regulations.

Dr. CRAWFORD. That is correct.

Mr. SCHIFF. Did it surprise you that the Department of Agriculture argued that even a policy statement was a preemption in the California case, if you are able to answer that, or did you expect that they would argue that?

Dr. CRAWFORD. You are getting me beyond my competence because that is, I think, a legal question which I am not qualified to comment on.

I believe they might not have addressed, though, the issue of the competency of policy memos, they just said they were preempting.

Mr. SCHIFF. With whatever they had. All right.

Thank you, Mr. Chairman. I yield back.

Mr. TOWNS. Thank you very much.

At this time I yield to Congressman Payne of New Jersey.

Mr. PAYNE. Thank you very much.

In your statement, Mr. Leonard, you said that there is a move to cut back the number of Federal inspectors, increase line speeds, hand over key public safety responsibilities to employees of the poultry processing firms.

Mr. LEONARD. That is correct.

Mr. PAYNE. You know, in the 1980's they did something similar to that in the S&L industry where they said they wanted to have less regulators, do more with less, efficiency, cutting back on expenditure and there was not the monitoring, and we see what occurred. In your opinion, if there is a cutback in the number of inspectors and these other things—and any of you could answer—what do you think that will do to the industry in general? Would it enhance it or detract from it?

Mr. LEONARD. I think it is important to point out that the problem with the S&L's in the 1980's, and the problem was a deregulatory effort. What we are seeing here with this new policy that they are considering: This has been distributed to all the regional offices for review and comment by the regional staff. It was developed in consultation with the poultry industry. It is a continuation of the deregulatory policies that have pretty much—have predominated policy considerations in the Department of Agriculture on food safety. So that what we are seeing here is simply a continuation of that.

I think what you will see is an increase in the cases of food poisoning. You will see more outbreaks similar to the E. coli problem 18 months ago. I don't know if you watched some of the recent television reports about problems in meat and poultry inspection, but one of the reports looked into the problem with turkey, and you heard Mr. Rominger talk about the new—what is it? Anyway, the new program on turkey inspection—what the new turkey inspection program amounts to is reducing the number of inspectors, and in one of those incidents that was caught on the hidden television camera, they were taking turkey carcasses and basically playing soccer with them on the floor of the processing plant.

You will simply find more of that going on because the only—it has always been very difficult for me to understand the logic in this, because the inspector on line in the plants is essentially your representative and my representative in making decisions about the food that I will eventually buy. I can't go into the plants, you can't go into the plants, so we rely on the inspector to do that, and he or she is our agent there, and once you remove our agent, then we have no protection.

Mr. PAYNE. And so therefore you feel that this trend is very serious.

We have heard some recent reports about shellfish, and fish in general but shellfish in particular, which is being harvested at the wrong time of the season and it actually could kill; I mean it is

very serious. Maybe anyone here could comment on your feeling of what is going on in the food industry in general, even the fact that hormones are used on certain kinds of, I guess, beef, and also, I guess, somehow vegetables are being treated—I don't know if you do it genetically, or I don't know what you do with a tomato, but there is an altering of the process scientifically to have larger products.

Where do you see all of this taken? Is it good business? Is it something that is safe? Is it something that we need to be cautious about? How do you see this whole new food processing business going, not particularly chicken necessarily, but in general, Dr. Crawford.

Dr. CRAWFORD. Yes, thank you. I serve on the FDA Food Advisory Committee, and we reviewed both the two substances you mentioned, the bioengineered tomato and also the milk-enhancing product. I believe that the data on those show that these are among the safest procedures in products we ever had to review.

You know, each new generation of these kind of products get away from the old ones that were toxic, like DDT, and I think personally bioengineering offers us an opportunity to produce not only more effective products but safer products, because if you can control the genetics involved, why would you pick something more toxic? You would always pick something that is less toxic than what else is on the market.

So I believe that FDA did a good job in both those cases and applaud them. Unfortunately, it took a long time. It took 9 years in one case and 5 in the other, but it probably was time well spent for the most part, and the next ones won't take that long.

Mr. LEONARD. I think if you look at the evidence that Dr. Crawford refers to, what it essentially says is, they couldn't find any reason not to do it, and I think what is happening is with something like BGH, for example, you are introducing chemicals that have a deleterious effect on the animal. We know that it shortens the productive life of the cow, we know it increases the level of disease in the cow, it strains the immune system. We don't know what the long-term effect of all of this is going to be.

The bioengineered products simply illustrate the fact that food processors now are really chemical companies and drug companies. Our food system is really a mechanism to enhance profits of those firms. There is no justification that has been presented in terms of the need for food in terms of shortages, impending shortages, or anything on that side.

What we have now is the idea that bioengineering is somehow going to enhance the food supply. There is no threat to our food supply that needs to be addressed by these kinds of mechanisms.

Ms. GOLODNER. I am not an expert on biotech, but I think you should know that both the Food and Drug Administration and the U.S. Department of Agriculture indicate that there are probably 81 million cases of foodborne illness in the United States every year. The people who are most affected are the old and the very young and those who have compromised immune systems.

However, there is a new food code that the FDA has released that emphasizes food safety at the retail level, and both agencies

are instrumental in implementing the HACCP system which should help in food safety problems.

But that certainly is not an answer to a problem that we have which is inherent, and that is to make sure that the food is inspected and that it arrives at the grocery store safely for consumers to purchase.

Mr. TOWNS. The gentleman's time has expired.

Mr. PAYNE. Thank you very much.

Mr. TOWNS. At this time I yield to Congressman Horn.

Mr. HORN. Thank you very much, Mr. Chairman.

I have enjoyed the testimony from each of you with your unique perspective.

Dr. Crawford, remind me, I have forgotten, was Secretary Lyng a Californian?

Dr. CRAWFORD. He was.

Mr. HORN. That is what I thought. Was he the one that initiated the original interest? Because I noticed in the testimony from the Deputy Secretary this morning they note 7 years later in 1988, at the request of some poultry industry members, FSIS again reviewed the policy on the use of the term "fresh." Was it the California fresh producers that essentially initiated that review?

Dr. CRAWFORD. No.

Mr. HORN. Was it your doing or the Secretary's doing?

Dr. CRAWFORD. It was my doing. We had visits from other producers that marketed fresh poultry, but they were not from California.

Mr. HORN. I note in your declaration that you said that the Secretary's instructions were, "Work it out and accommodate the National Broiler Council," and you pointed out that they were absolutely uncompromising, they are sort of like the NRA. So at that point, what were your options? Apparently, the Secretary just washed his hands of it. He got into this—and I have seen many an executive do this, say, "Who got me into this? I don't like all this noise. Work it out so we don't make a lot of headlines."

Dr. CRAWFORD. Well, I think—I think the guiding thing for him was that he was going out of office, and he was aware of that. My only option was to go the regulatory route or try to put it under some other larger rubric, yes. The meetings that I had with the industry on both sides, though, were cordial. They weren't threatening or intimidating, and I think maybe your comparison would not be the correct one.

Mr. HORN. Well, they obviously won the fight, and nobody even said boo to them.

Dr. CRAWFORD. Well, they certainly gained more time.

Mr. HORN. Usually if you are going out of office, you have got a chance to be a hero unless you want a job in private industry or something, and if that is motivating you, you sit there and supinely submit. But it sound like the Secretary, that was interested from the beginning, just sort of gave up on the fight instead of saying, "Hey this is nonsense, let's issue this regulation, let's issue this policy, let's implement it," and it was never implemented.

Dr. CRAWFORD. Well, I think he knew that, since there wasn't universal agreement within the industry, we would have to go the

regulatory route and he wasn't going to be around to see that through, because it was going to take years rather than weeks.

Mr. HORN. So you leave the timebomb for your successor.

Dr. CRAWFORD. Well, I didn't leave the timebomb for the successor, I was still there, I was the successor.

Mr. HORN. So anyhow, it just bothers me that there seems to be a failure of leadership then and now, but I gather eventually, with hearings like our two good chairmen are conducting, we will generate a little heat on truth and justice.

The only thing I would add is my favorite comedian's thoughts on this, one Mark Russell that used to play the piano for those of us who were on Capitol Hill 30 years ago. He says about this issue two sentences: I always thought that "fresh" meant the product has never been frozen. It turns out that all "fresh" means is that the chicken is dead. Then he notes, to satisfy us doubters, the chicken people should come out with more specific labeling: "it was fresh when we froze it;" "semi-fresh;" "freshly thawed;" and, "smells funny." And I must say that would be an advancement maybe over fresh versus frozen.

But I hope we do get, Mr. Chairman down to truth in advertising, which is what we are talking about here as well as safety.

Mr. TOWNS. Thank you very much, and thank you for letting us know there is almost fresh as well. Thank you.

At this time I yield to Congressman Peterson.

Mr. PETERSON. Thank you, Mr. Chairman.

I was sitting listening to all this, I haven't really focused on this much, but I am just beginning to wonder how much of this is a marketing issue and how much is other things. You know, the BST issue, we have companies in my State now that are getting more money for milk that they claim is BST free apparently because some people will pay for that even though nobody can tell for sure if it really is because it exists in ordinary milk and you just kind of have to take people's word for it, and I think we get into a slippery slope, I guess is what I am saying, when we get into this issue, and I am not so sure if people know what "fresh" means.

I think you said that, Ms. Golodner, that they can't tell the difference. You said that they could taste the difference. So I guess I have a couple of questions.

Do we have a lot of people complaining that they are buying chickens and then they get them home and they can tell by tasting them that they are not fresh? Are we getting a lot of calls? Is that why this has happened?

Ms. GOLODNER. Well, it is something that has come to the public's attention recently.

Mr. PETERSON. So they didn't know this until somebody told them?

Ms. GOLODNER. You see, when you go to a grocery store—and I don't know how many of you do your own shopping, but you go to the store, and if you are going to cook the chicken today or tomorrow, you buy a fresh chicken because it tastes better. If you are going to cook it next week, you buy it frozen and pay a little less.

Mr. PETERSON. I don't agree with that. I mean that is not how I approach it. Maybe I'm ignorant and I don't know the difference,

but I mean I think there are a lot of people that really don't know the difference, and I just wonder about this whole thing.

Can anybody tell me how many States have rules that require that there be labeling "fresh" and "frozen"? I mean does every State have this, or is it just a couple of States? Does anybody know?

Ms. GOLODNER. I don't know.

Mr. PETERSON. I don't think every State has this, do they?

Mr. LEONARD. I think what we are dealing with here is the fact that California is often far ahead of the rest of the States——

Mr. PETERSON. In protecting their market?

Mr. LEONARD. Well, no. They will tend to be more protective of consumer interests, and so they will often take the lead. Other States tend to go behind them.

Mr. PETERSON. Well, it depends on your point of view of whose interests you are protecting and whose responsibility it is on this, and, you know, you say there's 81 million cases of people getting—who said that?

Ms. GOLODNER. Foodborne illness, yes.

Mr. PETERSON. How many of those were caused by people not cooking the food correctly, can you tell me, and how many were caused because it was handled incorrectly?

I mean part of the problem is, you can, as the person who produces this, you can send this stuff to the store and if they don't handle right or if the person doesn't handle it right after they take it home, what can we do about it that produce the turkeys in the first place?

You know, it is my judgment that a lot of this problem is caused because people don't know how to cook these types of meat in the first place, and so what can we do about that, and how much money are we spending or are you spending to educate people on how to cook this stuff so that they don't get sick? That is the other side of this.

Ms. GOLODNER. Actually, there are a lot of programs now on trying to educate people about cooking food, but the burden should not be on the consumer to make sure that that food is safe——

Mr. PETERSON. Why not——

Ms. GOLODNER [continuing]. When they purchase it.

Mr. PETERSON. Why not? Why should the burden not be on the consumer? You know, in this society nobody is responsible for anything any more. I mean, you know, I don't buy that the consumer should not have some involvement in this.

Ms. GOLODNER. No. When you purchase a product, it should be safe.

Mr. PETERSON. Absolutely.

Ms. GOLODNER. However, when you bring it home, it is your responsibility to make sure that you clean it——

Mr. PETERSON. OK. So you are saying that the consumer does have some responsibility.

Ms. GOLODNER [continuing]. Or you refrigerate it or you freeze it or you cook it properly, absolutely. However, it is up to the Government and up to the store and up to the processor to make sure that it is safe in each one of their——

Mr. PETERSON. I am not so sure the Government can do this. I mean we can try, but I am not so sure that we have the ability

to make sure that everybody is going to be protected under every circumstance.

But do we know, out of these 81 million cases, how many were caused because of a problem with the inspection system and how many were caused because people didn't know how to handle it or cook it when they got it home? Do we have that information?

Ms. GOLODNER. No, I don't think that information is available.

Mr. PETERSON. Well, how can we make these decisions if we don't know?

Mr. LEONARD. Well, if you are going to protect the public and if you are concerned about public health, the one thing that you don't want to do is to bring contaminated food into your home or have contaminated food in the restaurant. The only way you are ever going to be sure of doing that is to make certain that the inspection program is being operated specifically for that particular purpose.

In the case of poultry, we should never have allowed fecal contamination to be considered a cosmetic blemish. Once you have fecal matter on a turkey or on a bird, that bird is contaminated, there is nothing you can do to clean it off. But the Department's rules now say that it is all right to have fecal matter on a bird as long as you wash it off some time. Now that is exposing the public to needless risk.

Mr. PETERSON. I agree with you that the system isn't perfect, but, you know, we haven't seen, at least as far as I am aware, that there has been some big deterioration in the quality of the inspection.

Mr. LEONARD. Oh, gosh, yes, look at the CDC data on foodborne illnesses, on the incidence of foodborne illness. Go back to 1960 and look at the increase in the incidence of foodborne illness. In those days it was 5 to 6 per 100,000. Today it is 27 per 100,000. We know very well there is a problem.

Mr. PETERSON. My time has expired, but I think that there is also some possibility that that could be because we are keeping track of things now and we are more sophisticated in being able to determine what illnesses. You know, if you go back and read the coroner reports in the 1800's about why people died, I mean you will see they died of consumption or, you know—so I mean to some extent we don't really know, that is the bottom line with a lot of this stuff, and I guess that is what we are trying to get at, is, I guess, and I am frustrated that we don't have much information about where this problem is being caused because I am not convinced it is always necessarily being caused within the industry, and I can tell you my producers are frustrated in this process as well as you are, because a lot of times what happens they have no control over, and, you know, they are doing the best they can on the other end. So I am just trying to say there is another side, I think, to this.

Mr. TOWNS. The gentleman's time has expired.

I yield one minute to the gentleman from California.

Mr. HORN. It dawned on me as I listened to this that the fresh frozen analogy, where it is in my background is, when I go into a restaurant to order fish and you say, "Is this fresh?" And the waitress sort of sheepishly looks at you and says, "Oh, well, it is fresh frozen."

Is there any analogy either scientifically where the problems are between the fresh frozen fish bit and the fresh frozen chicken bit? What are the problems there, and is that something the Department ought to be looking at? Does it have jurisdiction?

Dr. CRAWFORD. The Department of Agriculture does not have jurisdiction over fish. That is the National Marine Fisheries Service and the FDA. They share it. I think you will find that the labeling there will use terms like "fresh," "fresh frozen," and also "previously frozen."

Mr. SCHIFF. Does this mean that if we see on a restaurant menu "catch of the day," we should ask which day?

Mr. HORN. Which year? You might ask which year.

Mr. TOWNS. Thank you very much. We thank all three of you for your testimony. You have been extremely helpful.

I would like to call on our fourth panel: Mr. Bill Mattos, president of the California Poultry Industry Federation; Dr. Kenneth May, technical advisor to the National Broiler Council; and Mr. Larry Fanella, chairman of the National Turkey Federation.

Mr. FANELLA. Mr. Chairman, I would like to ask that the chair also swear in Mr. Ron Waters. Mr. Waters is chairman of the National Turkey Federation Technical and Regulatory Committee.

Mr. TOWNS. All right. Come forward.

Mr. MAY. Mr. Chairman, I have also asked if Mr. James Marsden from the American Meat Institute accompany me.

Mr. TOWNS. Fine.

Of course, you know it is the custom of this committee to swear in its witnesses. Raise your right hand.

[Witnesses sworn.]

Mr. TOWNS. All right. Take your seats. Let the record reflect that the witnesses have answered in the affirmative.

Let me begin by first thanking all of you for taking time out of your busy schedules to come and testify today. Let me remind the witnesses that your entire statements will be included in the record, and if you would summarize your statement within 5 minutes that would allow the members of the committee an opportunity to raise questions with you.

Why don't we start with you, Mr. Mattos.

STATEMENT OF BILL MATTOS, PRESIDENT, CALIFORNIA POULTRY INDUSTRY FEDERATION

Mr. MATTOS. Thank you, Chairman Towns, chairman Condit. My name is Bill Mattos, and I am the president of the California Poultry Industry Federation.

The California Poultry Industry Federation represents poultry producers in California. Many of our members also produce poultry in Oregon and Washington and sell poultry throughout the western United States. Our members employ over 25,000 men and women in what is probably the largest market for poultry in the country. Our members also believe in fair competition. They compete with each other and with producers from other parts of the country.

Fair competition requires a level playing field, and it requires an informed consumer. I am here today because the playing field is not level and because the consumer is misinformed. California consumers are buying and paying more for poultry that they are told

is fresh when it isn't fresh at all. This consumer fraud, amazingly, is sanctioned and encouraged by the Department of Agriculture. It is grossly unfair to consumers and to poultry producers.

The main two ways that producers compete is on price and on quality. Some consumers look for the best buy while others will pay a little more for poultry that is of higher quality. Go into any supermarket and you will find many choices and many different prices that correspond to those choices.

West coast poultry producers have a natural advantage for consumers who want fresh chicken because west coast producers are closer to west coast customers. By definition, our chicken is fresher. Not every consumer cares about this, but many do.

Producers in the southeast have certain advantages as well, largely related to price. Southeast producers pay their workers less and have access to less expensive feed than producers on the west coast. Their cost of production is less, and therefore their poultry is less expensive than west coast poultry. There are many consumers who will pay a bit more for fresh poultry.

Southeast producers have not been content in exploiting their natural cost advantage. Instead, they have embarked on a massive program to defraud those consumers who will pay more for fresh poultry, tricking consumers into believing that poultry is as fresh as west coast poultry.

Southeast producers label their chicken as fresh. They freeze it and ship it across the country in trucks as cold as zero or 1 degrees Fahrenheit, and then they thaw the poultry for sale. The consumer is never told that the poultry was frozen for periods as long as a week and then thawed for sale, and the consumer buys the poultry believing it is fresh.

A level playing field means consumers know the truth about what they are buying so that producers can compete fairly. An informed consumer must know the previously frozen southeastern poultry is not fresh, and that term is commonly understood by consumers.

When the truth is disclosed, many consumers will continue to by southeastern poultry, but they shouldn't be tricked into buying—into believing it is fresh when it is not.

If this deception was not standard practice, there would be no controversy. If the national producers didn't do it, they would have no reason to be concerned about California's law which they have vigorously challenged in court. Of course, they do engage in these practices, and that is why we are here today.

The reason poultry producers want to call frozen chicken fresh is that many consumers are demanding more and more fresh, never frozen food and they are willing to pay more for fresh, never frozen poultry, and if they know that the fresh labeled chicken they are paying for was actually a thawed out, previously frozen bird, they would have every right to be upset. This is fraud, and it is deliberate misrepresentation and false advertising.

Consumers learn about this practice, they tell us—when they learn about it, they tell us that thawed poultry isn't frozen, as we revealed in earlier consumer studies. It is unconscionable, after the Congress has spent the last 25 years enacting major consumer protection legislation of all kinds, that the Department of Agriculture

still allows poultry producers to deep freeze their chicken or turkey to 1 degree Fahrenheit and falsely call it fresh.

The actual temperature at which chicken freezes is 25 degrees and becomes hard as a rock. Thus, a so-called fresh USDA chicken could smash a car window, you could hammer a nail with it, and you could bowl with it.

Mr. Chairman, producers on the west coast don't freeze their fresh chicken, and we think it is wrong for southeastern producers who compete against our truly fresh products to call their frozen and/or thawed chicken fresh.

Whatever the private economic consequences for companies that sell chicken, the public interest demands that the Government's food labeling policy be accurate and does not foster deception by producers. Their chicken has been frozen solid, ours hasn't.

Call me a radical, but I think consumers deserve to know the difference so that they can make an honest choice. We welcome fair competition from other poultry producing regions of the country. We believe in interstate commerce, but the National Broiler Council would like to believe that big bad California is beating up on the poor beleaguered poultry producers from other States. This is a joke to us.

The giant producers have a huge share of our market. Under the California law they challenge, they would still have every opportunity to sell chicken in our State. They just couldn't call frozen chicken fresh, that's all. If they wanted to continue selling fresh chicken, all they would have to do is transport their "fresh" label product at chilled but nonfrozen temperatures just like we do. The consumer's right to know clearly outweighs the company's right to make an unfair profit.

The truth of the matter is that southeastern poultry producers sell as much poultry that is frozen or not identified as fresh as they do poultry that is fresh. The consumer is willing to buy both fresh and frozen poultry. As for a claimed concern for safety, the scientific literature agrees that harmful bacteria growth stops when chicken is chilled below 32 degrees but it doesn't freeze solid until chilled below 25 degrees.

Storing above 32 degrees is not dangerous by any means. Most home refrigerators are not set above 32 degrees—are set above 32 degrees. So the safe nonfrozen temperature range for transporting fresh chicken is between 26 and 32. As you will see on the Tyson's package, it says right here, "Please keep"—"hold the temperature just above the freezing point of poultry, 28 to 32 degrees."

And I will wrap up.

Mr. TOWNS. Yes. Thank you.

Mr. MATTOS. I just basically wanted to leave you with the fact that, you know, we believe in truth in labeling, that fresh is fresh and frozen is frozen. The National Broiler Council will tell you that fresh should be 15 degrees, and I want to point out the chicken that Mr. Puck had up here was about a 20-degree chicken, and so freezing it even harder than that is absurd to us.

[The prepared statement of Mr. Mattos follows:]

TESTIMONY OF BILL MATTOS, PRESIDENT, CALIFORNIA POULTRY INDUSTRY FEDERATION BEFORE THE GOVERNMENT OPERATIONS SUBCOMMITTEES ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS AND INFORMATION, JUSTICE, TRANSPORTATION AND AGRICULTURE

U.S. HOUSE OF REPRESENTATIVES WASHINGTON, D.C. JUNE 16, 1994

Thank you Mr. Chairman. My name is Bill Mattos and I am the President of the California Poultry Industry Federation.

The California Poultry Industry Federation represents poultry producers in California. Many of our members also produce poultry in Oregon and Washington and sell poultry throughout the Western United States. Our members employ over 25,000 men and women in what is probably the largest market for poultry in the country.

Our members believe in fair competition. They compete with each other, and with producers from other parts of the country.

Fair competition requires a level playing field and it requires an informed consumer. I am here today because the playing field is not level, and because the consumer is misinformed. California consumers are buying and paying more for poultry that they are told is fresh, when it isn't fresh at all. This consumer fraud is, amazingly, sanctioned and encouraged by the federal government. It is grossly unfair to consumers and to poultry producers.

The main two ways that producers compete is on price and quality. Some consumers look for the best buy, while others will pay a little more for poultry that is of a higher quality. Go into any supermarket and you will find many choices and many different prices to correspond to those

choices.

West Coast poultry producer have a natural advantage for those consumers who want fresh chicken because West coast producers are closer to West coast customers. By definition, our chicken is fresher. Not every consumer cares about this, but many do.

Producers in the Southeast have certain advantages as well, largely related to price. Southeast producers pay their workers less and have access to less expensive feed than producers on the West coast. Their cost of production is less, and therefore their poultry is cheaper than West coast poultry.

There are many consumers who will pay a bit more for fresh poultry. Southeast produces have not been content in exploiting their natural cost advantage, instead they have embarked on a massive program to defraud those consumers who will pay more for fresh poultry, tricking consumers into believing their poultry is as fresh as West coast poultry. Southeast producers label their chicken as "fresh," they freeze it and ship it across the country in trucks that are as cold as zero degrees Fahrenheit, and then they thaw the poultry for sale. The consumer is never told that the poultry was frozen for periods as long as a week, and then thawed for sale and the consumer buys the poultry believing that it is fresh.

A level playing field means that consumers know the truth about what they are buying so that producers can compete fairly. An informed consumer must know that previously frozen Southeastern poultry is not fresh -- as that term is commonly understood. When the truth is disclosed, many consumers will continue to buy Southeastern poultry, but they should not be

tricked into buying poultry believing it is fresh when it's not.

If this deception was not standard practice, there would be no controversy. If the national producers didn't do it, they would have no reason to be concerned about California's law which they have vigorously challenged in court. Of course they do engage in these deceptive practices, and that's why we're here today.

The reason poultry producers want to call frozen chicken fresh is that many consumers are demanding more and more fresh, never-frozen food. And they're willing to pay more for fresh, never-frozen poultry. And if they know that the fresh labeled chicken they're paying more for was actually some thawed out, previously frozen bird, they'd have every right to be upset.

This is fraud, and it's deliberate misrepresentation, and it's false advertising. Consumers learn about this practice, they tell us that thawed poultry isn't frozen.

It's unconscionable, after the Congress has spent the last 25 years enacting major consumer protection legislation of all kinds, that the Department of Agriculture still allows poultry producers to deep freeze chicken as low as 1 degree Fahrenheit and falsely call it fresh. The actual temperature at which chicken freezes solid is 25 degrees. Thus a so-called fresh USDA chicken could smash a car window. You could hammer a nail in the wall with it. You could bowl with it.

Mr. Chairman, producers on the West coast don't freeze their fresh chicken. And we think it's wrong for Southeastern producers who compete against our truly fresh products to call their frozen

and/or thawed chicken fresh. Whatever the private economic consequences for companies that sell chicken, the public interest demands that the government's food labeling policy be accurate and does not foster deception by producers.

Their chicken has been frozen solid, ours hasn't. Call me a radical, but I think consumers deserve to know the difference so they can make an honest choice.

We welcome fair competition from other poultry producing regions of the country. We believe in interstate commerce. But the National Broiler Council would have you believe that big, bad California is beating up on the poor, beleaguered poultry producers from other states. This is a joke! The giant producers have a huge share of our market. Under the California law they challenged, they would still have every opportunity to sell chicken in our state. They just couldn't call frozen chicken fresh. That's all. If they wanted to continue selling fresh chicken, all they'd have to do is transport their fresh labeled product at chilled but nonfrozen temperatures, just like we do. The consumers' right to know clearly outweighs the companies' right to make an unfair profit.

The truth of the matter is that Southeastern poultry producers sell as much poultry that is frozen or not identified as fresh as they do poultry identified as fresh. The consumer is willing to buy both fresh and frozen poultry.

As for a claimed concern for safety, the scientific literature agrees that harmful bacteria growth stops when chicken is chilled below 32 degrees. But it doesn't freeze solid until chilled below 26

degrees. Storing above 32 degrees is not dangerous by any means. Most home refrigerators are set above 32 degrees. So the safe, nonfrozen temperature range for transporting fresh chicken is between 26 and 32 degrees. There's no safety issue here. National producers don't need to freeze their chicken. They do, though, in order to have maximum time flexibility.

The National Broiler Council will also tell you that "fresh is not the opposite of frozen." They want us to believe that food can be fresh and frozen at the same time. They want to confuse the difference between fresh and frozen by saying that other factors, such as taste and smell, also determine whether something is fresh.

As important as those factors are, they don't distinguish fresh from frozen in the minds of most consumers. Frozen chicken still tastes good. But that doesn't mean it's fresh. Fresh means never frozen. That's what consumers think, that's what common sense says, that's what food producers of all kinds tell us in their advertising -- and that's what the dictionary says. "Fresh" as in "fresh food" means "not preserved, as by canning, smoking or freezing."

Finally, let me disagree once more with the Broiler Council. They will tell you this problem needs further study. Their position is, why fix a problem when you can study it? But the laws of nature haven't changed since the last time USDA investigated the freezing point for chicken six years ago. It's still 25 degrees, just as it was in 1988, just as it was in 1888, and just as it'll be in the year 2088.

The federal policy needs to be corrected. USDA should immediately set the freshness standard

at 26 degrees because consumers have the right to know whether the chicken and poultry they're buying is fresh or previously frozen and they have a right to get exactly what they pay for.

I'm happy to say that the Consumer Federation of America, Consumers Union, The Washington Post editorial page, Turkey World Magazine, Meat and Poultry Magazine, the states of New York, Oregon, Maine, Arizona, Puerto Rico and many others agree with our position. I am hopeful that your subcommittees will too.

Thank you.

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Mr. TOWNS. All right. Thank you very much for your testimony. Dr. May.

STATEMENT OF KENNETH N. MAY, Ph.D., ON BEHALF OF THE NATIONAL BROILER COUNCIL, ACCOMPANIED BY JAMES MARSDEN, AMERICAN MEAT INSTITUTE

Dr. MAY. Thank you.

I appear this morning on behalf of the National Broiler Council, the American Meat Institute, and the Arkansas Poultry Federation. I am accompanied today by Dr. James Marsden of the American Meat Institute.

I am pleased to have this opportunity to set the record straight about an issue that has received an unfortunate amount of rhetoric and misleading media attention and other publicity in recent months to the detriment of the entire U.S. poultry industry and to American consumers.

The objective of poultry companies is to produce and distribute products that are not only meaningfully labeled but remain wholesome for the preparation and enjoyment of consumers. The processing and shipping methods employed by the industry for more than 25 years make it possible for companies to achieve this objective regardless of product destination.

Contrary to what some would have you believe, poultry processors do not market frozen chicken as fresh and have no commercial incentive to do so. Also contrary to what the press and others have been telling consumers lately, establishing the criteria for measuring a poultry product's freshness is not a simple matter of temperature alone.

Since at least 1981, it has been USDA's consistent policy that poultry products may be labeled as fresh so long as they have not been frozen. In this regard, a product is frozen under USDA regulation's if it has reached a temperature of zero degrees Fahrenheit at its center.

In 1988, as has been discussed here today, USDA issued a new policy memorandum revising the agency's fresh labeling requirements as applied to meat and poultry products. At that time, the agency has decided to prohibit the labeling of products that has reached an internal temperature of 26 degrees or less as fresh. But USDA quickly rescinded that policy before it took effect. To the best of our knowledge, USDA has not considered changing this policy since 1988 until the present time.

Much of the rhetoric and theatrics that have surrounded this issue in recent months have suggested that poultry products that have reached internal temperatures of 25 degrees or 26 degrees Fahrenheit should be considered as frozen.

I am pleased to refer the committee to perhaps the most comprehensive literature review in this area entitled, "Superchilling of Poultry Meat," published by Dr. W.J. Stadelman of Purdue University. Dr. Stadelman cites in excess of 50 studies concerning poultry and meat freezing, preservation, and storage. Not one of these studies supports the premise that fresh and frozen are opposite conditions or that the product's freshness can be measured only by its temperature.

Whether a product is fresh depends on several factors including taste, aroma, bacterial quality, and nutritional characteristics. One obvious characteristic of any fresh chicken product, which is true of other fresh products like milk or vegetables or anything else, is that it has a limited shelf life. This is true because all fresh meat and poultry has bacteria which continue to grow even at cold temperatures, eventually causing spoilage. This process of bacterial growth does not occur when chicken is preserved by freezing, drying, sterilizing, irradiation—sterilizing, irradiation or canning.

Interestingly, bacterial growth does not stop at temperatures below 26 degrees Fahrenheit, which many people here today have touted as a point below which they claim chicken is frozen. In fact, it does not stop at 24 or 22 or 20 or even 18 degrees Fahrenheit. Bacterial growth does not stop until the product's internal temperature reaches about 14 or 15 degrees Fahrenheit. If one were to choose any specific temperature other than the zero degree Fahrenheit temperature now required by USDA for defining chicken as frozen, then 14 degrees Fahrenheit would be the only scientifically valid one for this reason.

Any chicken that has a limited shelf life and will spoil because of bacterial growth should be considered as fresh. Frozen chicken will not spoil from bacterial growth. It would not be in the best interests of consumers to declare that chickens held at temperatures below the mid-20 degrees Fahrenheit as frozen. It also would not be scientifically valid. Such poultry is clearly still fresh.

Coincidentally, the same regulations and policy statement that prohibit the labeling of poultry as fresh if the product has been frozen do not establish any temperature criterion for the labeling of red meat as fresh. Meat products may be called fresh so long as they have not been cured canned, hermetically sealed, dried, or chemically preserved. USDA was presumably true to the science when it adopted its freshness definition for red meat products.

I thank you for this opportunity to clarify this situation.

Thank you.

[The prepared statement of Dr. May follows:]

Prepared Statement of
Kenneth May, Ph.D.
Regarding Labeling of Fresh Poultry
on behalf of
National Broiler Council,
American Meat Institute, and
Arkansas Poultry Federation

Before Subcommittees on Human Resources and Government Relations,
and Information, Justice, Transportation and Agriculture
House of Representatives
Committee on Government Operations

June 16, 1994

Good morning. My name is Kenneth May and I serve as Technical Advisor to the National Broiler Council. I am accompanied by James Marsden, Vice President, Scientific and Technical Affairs for the American Meat Institute and President of the American Meat Institute Foundation. I have provided the Subcommittee with a copy of my curriculum vitae which outlines my educational background, research, and practical experience both in academia and in the poultry industry over the last 40 years with issues of chemistry and microbiology involved in the chilling and processing of poultry and poultry products. A copy of Dr. Marsden's curriculum vitae summarizing his more than 20 years experience in the meat industry has also been provided.

I appear this morning on behalf of the National Broiler Council, American Meat Institute and Arkansas Poultry Federation. As you probably know, these three organizations are plaintiffs in a lawsuit that, at least in part, precipitated today's proceeding. The National Broiler Council is a national trade association that represents the producers and processors of over 90 percent of the broiler/fryer chickens marketed in the United States. The American Meat Institute is a national trade association that represents the producers and processors of meat, meat products, turkey, and turkey products marketed in the United States. The Arkansas Poultry Federation is a trade association that represents Arkansas entities involved in commerce in turkeys, broilers, breeders, and commercial laying flocks.

I am pleased to have this opportunity to set the record straight about an issue that has received an unfortunate amount of rhetoric and misleading media attention and other publicity in recent months to the detriment of the entire U.S. poultry industry and American consumers. The objective of poultry companies is to produce and distribute products that are not only meaningfully labeled, but remain wholesome for the preparation and enjoyment of consumers. The processing and shipping methods employed by the industry for more than 25 years make it possible for companies to achieve this objective regardless of product destination.

Contrary to what some would have you believe, poultry processors do not market frozen chicken as fresh, and have no commercial incentive to do so. Also contrary to what the press and others have been telling consumers lately, establishing the criteria for measuring a poultry product's "freshness" is not a simple matter of temperature alone. Product freshness is a condition in which a product exhibits various characteristics. Although the temperatures to which a product is subjected during storage and distribution can affect its freshness, temperature alone does not determine freshness.

USDA Regulation of Fresh Poultry Labeling

As you may know, poultry products produced under U.S. Department of Agriculture inspection may not be marketed until their labels have been approved by USDA officials in Washington, D.C. The labels are prepared in accordance with USDA regulations and are then submitted to the agency for review. Once the labels have been approved for use, they may be applied to products.

USDA typically adopts regulations designed to ensure that products distributed in interstate commerce are properly labeled -- that is, not misbranded. In addition, to enable USDA label reviewers to respond to questions about the applicability of the labeling regulations and to adapt to specific situations that may arise as product development and marketing practices evolve, the agency periodically issues Policy Memoranda. These interpretations of the law and existing regulations are needed to guide government label reviewers, USDA inspectors, and the regulated industry to ensure that products distributed

throughout the United States are labeled and regulated in a uniform fashion.

Since at least 1981, it has been USDA's consistent policy that poultry products may be labeled as fresh so long as they have not been frozen. In this regard, a product is "frozen" under USDA's regulations if it has reached a temperature of 0° F. at its center. Actually, this had been USDA's policy even before 1981 but it had not been committed to the form of a Policy Memorandum until that time.

In 1988, USDA issued a new Policy Memorandum revising the agency's fresh labeling requirements as applied to meat and poultry products. At that time, the agency had decided to prohibit the labeling of products that had reached an internal temperature of 26° F. or less as fresh. But USDA quickly rescinded that policy statement before it took effect, noting as follows:

> The agency has now decided, after much deliberation on this issue, not to limit the use of the term "fresh" on unprocessed poultry products based on an internal temperature with the exception as defined by the current regulations, i.e., product is above 0° and below 40° F., and has not been previously frozen at or below 0° F. This decision is predicated on the belief that it is not practical under existing marketing strategies and distribution patterns, to define "fresh" in terms of internal temperature beyond the scope of the current regulations, nor is it practical to define consumer expectations for poultry products labeled as "fresh". The consumer is the best judge of preference in chilling temperatures for unprocessed poultry products labeled as "fresh," and therefore the marketplace is best suited for making this type of decision.

To the best of our knowledge, USDA has not considered changing this policy since 1988. Neither are we aware of any consumer complaints or other reasons why the existing policy has not worked very well to ensure that poultry products are properly labeled and distributed without jeopardizing product wholesomeness. Indeed, even USDA's reconsideration of this policy in 1988 was in the context of an industry debate about the effects of the existing labeling policy on certain processing techniques and marketing practices, not because of consumer concerns.

The only reason USDA's fresh poultry labeling policy has become the focus of attention now is because of the law that the state of California enacted last year prohibiting use of the term "fresh" to describe poultry that has reached 25° F. or less at its center; the California law also prohibited the labeling of poultry as "fresh" if the products had been held in average air temperatures at or below 25° F. for 24 hours or more, regardless of the products' temperature. The California law, which differed from the federal requirements applicable to all poultry products shipped throughout the country, was intended to make it difficult or even impossible for fresh poultry processed in other states to enter California. The products simply could not reach the state in time to meet the 24 hour threshold without jeopardizing product quality, and California's legislature knew it.

Because the California requirement was both in addition to and different from the federal requirements -- and because it interfered with the ability of poultry processors from outside California to market their products in that state -- the rest of the industry

challenged the California law in the United States District Court in Sacramento. USDA, seeking to preserve uniformity in the labeling of products under that agency's jurisdiction, joined as amicus curiae in support of the industry's position that the California law is pre-empted by federal law. The judge agreed and enjoined the state from enforcing it. The state and the California Poultry Industry Federation, who entered the case at the District Court level in support of California, have appealed to the United States Court of Appeals for the Ninth Circuit where the case is currently pending.

Please allow me to make clear that the industry's challenge to the California law was initiated to reinforce the fundamental legal principle that no state may impose a labeling requirement for poultry that is different from or in addition to federal requirements. Federal law expressly prohibits the states from inhibiting the free movement of USDA inspected products in this way.

Because of the California dispute, however, USDA has announced a review of the agency's current requirements. If rulemaking to modify the requirements is ultimately initiated, the industry will certainly participate in that process. What is most important, though, is that the labeling policies affecting products that are produced and shipped under a uniform set of federal requirements be developed by the federal government, and not by 50 different states trying to protect their local markets from out-of-state competition.

Research Concerning Freezing Temperatures of Raw Poultry

Much of the rhetoric and theatrics that have surrounded this issue in recent months have suggested that poultry products that have reached internal temperatures around 25° or 26° F. are considered to be frozen. Further, it has been suggested that frozen is the opposite of fresh. As earlier indicated, however, a product's freshness may be affected by the temperatures to which it has been subjected, but is not solely determined by those temperatures.

Nonetheless, I am pleased to refer the Subcommittees to perhaps the most comprehensive literature review in this area, "Superchilling of Poultry Meat," published by W.J. Stadelman of Purdue University. Dr. Stadelman cites in excess of 50 different studies concerning poultry and meat freezing, preservation and storage. Not one of these studies supports the premise that fresh and frozen are opposite conditions, or that a product's freshness can be measured only by its temperature.

Of particular significance, Dr. Stadelman explains that poultry meat does not freeze at 32° F. Indeed, it does not freeze at any single temperature, but over a range of temperatures. For example, he explains that water freezes at 32° F., poultry begins to freeze at approximately 28° F., the growth of organisms that cause spoilage of poultry products continues until the product reaches approximately 14° F., and practically all water molecules in poultry freeze at approximately 0° F. USDA chose this latter point as the only objective measure for purposes of enforcing its poultry freezing requirements.

To explain further, freezing is the transformation of water from a liquid to a solid form. In pure distilled water at standard atmospheric conditions, this occurs at 32° F. Chicken tissue (including muscle, skin, fat, and connected tissue) is not made up of pure distilled water, but is rather a complex mixture of protein, fat, water and minerals. In such a mixture, there is no sharply defined temperature at which the tissue freezes. Rather, there is a large range of temperatures at which various portions of the water are in crystalline (ice) form.

Criteria for Labeling Raw Poultry as Fresh

As I already mentioned briefly, whether a product is fresh depends on several factors, including taste, aroma, bacterial quality, and nutritional characteristics. One obvious characteristic of any fresh chicken product is that it has a limited shelf life. This is true because all fresh meat and poultry has bacteria which continue to grow even at cold temperatures eventually causing spoilage. This process of bacterial growth does not occur when chicken is preserved by freezing, drying, sterilizing, irradiation or canning.

Put another way, poultry has many indicia of freshness apart from whether the water molecules in the product are fully frozen. These include the growth of bacteria in the product, the aroma of the product, the onset of rancidity, the taste of the poultry, and the temperature at which the first molecules begin to freeze. In this regard, it is an attribute of fresh poultry that bacterial growth can cause spoilage or adulteration. Interestingly, bacterial growth does not stop at temperatures below 26° F. which some have touted as a point below which they claim chicken is frozen. In fact, it does not stop at 24° or 22° or 20° or even 18° F. Bacterial growth does not stop until the product's internal temperature reaches about 14° F.

If one were to choose any specific temperature other than the 0° F. now required by USDA for defining chicken as frozen, then 14° F. would be the only scientifically valid one for the reasons stated. Any chicken that has a limited shelf life and will spoil because of bacterial growth should be considered as fresh. Frozen chicken will not spoil from bacterial growth. It would not be in the best interests of consumers to declare that chicken held at temperatures below the mid-twenty degrees Fahrenheit is frozen. It also would not be scientifically valid. Such poultry is clearly still fresh.

I mentioned that the poultry industry has utilized techniques for more than 25 years that help ensure the marketing of wholesome products throughout the country. Because product temperatures will rise during the packaging process, Good Manufacturing Practice procedures dictate that the temperatures of the whole bird be quickly reduced to inhibit microbial growth. This process does not, however, freeze the product. Nor does the process in any way affect product quality, other than favorably.

Coincidentally, the same regulations and policy statement that prohibit the labeling of poultry as fresh if the product has been frozen do not establish any temperature criterion for the labeling of red meat as fresh. Meat products may be called fresh so long as they have not been cured, canned, hermetically sealed, dried, or chemically preserved. USDA was presumably true to the science when it adopted its freshness definition for red meat products.

CONCLUSION

In short, USDA's policies governing the labeling of poultry products as fresh and frozen have been in effect since at least 1981. The only time these policies have been challenged has been in the context of industry competitive disputes. At no time, however, has there been serious concern about the effectiveness of these policies at ensuring that consumers receive properly labeled, wholesome products with reasonable shelf lives.

Determining a product's freshness is a complicated matter, and not one that can or should be resolved by the arbitrary selection of any one temperature number. Temperature affects product freshness, but it does not determine it and cannot be used to measure it.

We do not object to USDA's reviewing its freshness labeling policy or any

other regulatory policy; indeed, the agency is encouraged to do this periodically to keep its policies current. But it is the federal government, and not 50 different states, that should develop the policies that are to be applied to products distributed throughout the country. Our only admonition is that, when it comes to issues that are primarily technical in nature, the best science should be brought to bear.

Thank you for this opportunity to appear today. I would be pleased to respond to any questions.

Mr. TOWNS. Thank you very much, Dr. May, for your testimony as well.

Mr. Fanella.

STATEMENT OF LARRY FANELLA, CHAIRMAN, NATIONAL TURKEY FEDERATION, ACCOMPANIED BY RONALD O. WATERS, CHAIRMAN, TECHNICAL AND REGULATORY COMMITTEE

Mr. FANELLA. Thank you, Mr. Chairman. Chairman Towns, Chairman Condit, thank you for the opportunity to testify here today.

NTF has submitted a written statement that I would request be entered as part of today's hearing record.

Mr. TOWNS. Without objection.

Mr. FANELLA. My name is Larry Fanella, and I am the chairman of the National Turkey Federation. The NTF represents every major American turkey processor as well as turkey growers, breeders, and hatchery owners. NTF is the only national trade association representing the turkey industry exclusively.

NTF is here today because our members believe it is time to move beyond the current contentious debate and move toward the scientific determination of a single national definition of fresh and frozen poultry. In the interim, NTF believes it is equally imperative that USDA continue to enforce its existing definitions of fresh and frozen and apply them on a national basis.

NTF in 1991 and 1994 adopted a policy that affirmed the Federation's support for the current Federal rule and for the Federal primacy in such labeling matters. However, the executive committee recognized that consumers might be confused by some aspects of the current USDA definitions of fresh and frozen, so the executive committee and board of directors have voted to support a USDA study of the issue.

We are glad to hear that California has corrected the discrepancy in State law which allowed retailers to chill poultry to 5 degrees. However, we would like to emphasize that this action was taken in part because NTF pointed out the existence of the double standard in Federal court.

There has been much discussion in this committee and elsewhere about the need to modernize USDA's poultry meat inspection system. NTF, USDA, and, as far as we know, all poultry trade associations agree that any revision to the inspection system should be based on sound, generally accepted scientific data and not on emotional considerations. The same principles apply to the fresh frozen regulation. They should be science based.

The National Turkey Federation believes additional studies are needed because there is no definitive scientific evidence, that the NTF knows of, that would indicate an appropriate temperature for delineating between fresh and frozen.

There has been discussion this morning and on into this afternoon that 26 degrees is the point at which poultry freezes. Well, we know of no scientific research studies to support this, and we suggest that this committee ask FSIS or California to provide any such research which will support this conclusion.

We know for certain that poultry does not freeze at 32 degrees, and we know that the organisms that can cause poultry spoilage

continue to multiply until poultry is chilled to at least 15 degrees. If poultry is shipped at 26 degrees over long distances, the margin for error in detecting food safety is razor thin. Poultry processors cannot guarantee absolute food safety if product is shipped at a temperature at which spoilage organisms can multiply. In the interim, we must maintain the current standard. The California law, as written, will not absolutely ensure the safety of fresh turkey and other fresh poultry products shipped long distances. The current USDA standard would. Until USDA can establish a new standard scientifically, NTF believes USDA should err on the side of caution in protecting consumers. Above all, we must not let emotion or pseudo-science rule the debate.

For example, the California Poultry Industry Federation recently conducted a poll that showed California consumers support the intent of the California law. Well, that may be, but consumer polling without science cannot be the basis for USDA regulations. NTF members also strongly believe that the Federal standard for labeling must preempt State standards. To do otherwise is to invite chaos, and here's why.

The California law, regardless of its supporters' intentions, creates an interstate trade barrier because it is so difficult to ship poultry over long distances at temperatures above 25 degrees. The law effectively prevents turkeys or other poultry products processed outside California from being sold in California as fresh. The California law will deny consumers in that State the benefit of free market competition. If California uses its own standard, California processors would be able to set fresh poultry prices without fear of being undercut by market competition.

USDA should not allow and Congress should not condone the practice of erecting interstate trade barriers. If the California law stands, what is to stop other States from following suit? Soon you could have 50 different labeling standards. Even California itself could find markets in Hawaii, Nevada, Utah, and Oregon cutoff by State legislation.

In conclusion, NTF finds it unfortunate that this issue is still not resolved. The whole issue could be put to rest if USDA conducts the research necessary to establish a true standard for differentiating between fresh and frozen poultry and then sets clear national labeling guidelines through the rulemaking process.

Thank you again for the opportunity to testify, and I will be happy to answer any questions.

[The prepared statement of Mr. Fanella follows:]

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Statement of the National Turkey Federation

to the Subcommittees on

Human Resources and Intergovernmental Relations
and
Information, Justice, Transportation and Agriculture

Committee on Government Operations

Presented by
Larry Fanella, Chairman

June 16, 1994

Chairman Towns, Chairman Condit, thank you for the opportunity to testify here today.

My name is Larry Fanella, and I am the chairman of the National Turkey Federation. The National Turkey Federation represents every major American turkey processor as well as turkey growers, breeders and hatchery owners. NTF is the only national trade association representing the turkey industry exclusively.

NTF is offering testimony today because our members believe it is time to move beyond the current contentious debate surrounding the fresh-frozen issue and to move toward the scientific determination of single, national definitions of "fresh" and "frozen" poultry based on sound scientific data rather than emotional arguments and marketing concerns. In the interim, NTF believes it is equally imperative that USDA continue to enforce its existing definitions of "fresh" and "frozen" and apply them on a national basis.

It might be beneficial to review briefly the history of the "fresh-frozen" issue and to explain NTF's current policy.

History of Issue and NTF Policy

Current USDA policy allows use of the term "fresh" on poultry, provided the poultry product never has been chilled to a temperature of 0 degrees Fahrenheit or colder nor allowed to warm to a temperature of 40 degrees or more. Poultry chilled to 0 degrees or below must be labeled "frozen."

In 1988, USDA considered revising the use of the terms "fresh" and "frozen" so that poultry chilled to 26 degrees or below would have to be considered "frozen." USDA

ultimately decided not to change the definition of "fresh" because the scientific data was not available to determine the exact temperature at which poultry becomes "frozen."

USDA policy applies to all poultry products packaged for interstate commerce.

In 1991, at the request of its members, NTF staff began evaluating the history of and scientific basis for current USDA policy. On the basis of staff findings, NTF's Executive Committee adopted policy that affirmed the federation's support for the current federal rule and for federal primacy in such labeling matters. However, the Executive Committee recognized that consumers might be confused by a definition that allowed a turkey chilled to 1 degree to be labeled as "fresh," so the Executive Committee voted to support a USDA study of the issue.

Meanwhile, in 1993, the California General Assembly passed legislation prohibiting any poultry product sold in California from being labeled or advertised as "fresh" if it ever has been chilled to a temperature of 25 degrees or less. Poultry that has been held at an ambient temperature of 25 degrees or less for more than 24 hours also could not be labeled or advertised as "fresh," regardless of the bird's lowest internal temperature.

The California Assembly may have been disingenuous in its action. The law it passed applies only to the handling and labeling of wholesale poultry products. California retailers are still allowed under a separate law to accept wholesale poultry labeled as "fresh" and then chill that poultry to a temperature of 5 degrees indefinitely while continuing to label it as "fresh." This means there is only a five-degree difference between the federal and state

retail labeling rules, which makes NTF wonder why so many Californians express indignation at the current federal standard.

Why does this double-standard exist? By requiring a higher temperature for wholesale shipment and labeling, California has now made it difficult for out-of-state processors to ship poultry into California and label it as "fresh." But, retailers are given much more latitude in the way they chill the exact same "fresh" poultry. This double-standard indicates that the California law is not based on science and undermines the claims of many Californians that they are only interested in protecting the consumer.

A bill has been introduced this year in the California Assembly to make the retail law conform to the wholesale law, but the legislation was introduced only after NTF pointed out in federal court the existence of the double-standard.

After the California "fresh-frozen" law was passed, the National Broiler Council and others challenged the California law in court, arguing that federal labeling rules pre-empt the California legislation. NTF filed an amicus curiae brief in the case, also arguing for federal pre-emption and pointing out the discrepancy between the California wholesale and retail laws. Both a federal district court and an appellate court in California since have ruled the California law is invalid and prohibited the state from enforcing it.

NTF's Board of Directors in January of this year revisited the "fresh-frozen" question, adopting a resolution re-affirming support for a single, federal labeling rule. The Board also authorized NTF to assist USDA in any effort to revise the rule.

The Need for Scientific Data

There has been much discussion in the last year about the need for USDA to modernize the poultry and meat inspection system. NTF's basic policy on any revisions to the inspection system is that they should be based on sound, generally accepted science and not on any emotional considerations. This position is advocated by USDA and, to our knowledge, by the California Poultry Industry Federation.

The same principles apply to the fresh-frozen regulation -- it should be science based. As is made clear by its 1991 and 1994 policies, the National Turkey Federation does not believe the data exists to make an accurate determination of the difference between "fresh" and "frozen" poultry. Additional studies are absolutely necessary because there is no definitive scientific evidence that NTF knows of that would indicate an appropriate temperature for delineating between "fresh" and "frozen".

We know for certain that poultry does not freeze at 32 degrees, the temperature at which water freezes. While we know that poultry begins to freeze at 28 degrees, we also know that the organisms that can cause poultry spoilage continue to multiply until poultry is chilled to at least 15 degrees. If poultry is shipped at 26 degrees over long distances, the margin for error in protecting food safety is razor thin. Poultry processors cannot guarantee absolute food safety if product is shipped long distances at a temperature at which spoilage organisms can still multiply.

What we still do not know is the exact temperature at which all water molecules in

poultry freeze. Evidence exists that such freezing occurs somewhere between 0 and 10 degrees, but the precise temperature eludes us.

The National Turkey Federation believes that this is where USDA should focus its research. When we know the exact temperature at which all water molecules freeze in poultry, then we will know the exact temperature at which a turkey or any other poultry product should be labeled as "frozen."

Maintaining the Current Standard

USDA officials have said they will review the current standard to see if a new federal definition of "fresh" and "frozen" is needed. In accordance with its policy, NTF is ready to assist with the effort where necessary. We would like as much as anyone to put this contentious issue behind the industry.

However, NTF and its members will object strongly to any new standard that is not based on sound science. Until the scientific evidence is generated to set a new federal standard, NTF and its members urge USDA in the strongest possible terms to maintain the current standard of 0 degrees as the point at which poultry is considered "frozen."

The California law would not absolutely ensure the safety of "fresh" turkey and other "fresh" poultry products shipped long distances. The current USDA standard would. Until the evidence exists to set a standard for "fresh" that is both safe for the consumer and more scientifically exact, NTF believes USDA should protect consumers and maintain the lower

temperature.

Above all, we must not let emotion or pseudo-science to rule the debate. For example, the California Poultry Industry Federation recently conducted a poll that showed California consumers support the intent of the California law. We have no reason to doubt the accuracy of the poll, but consumer polling and emotion cannot be the basis for USDA regulations. Science alone must dictate the final rules.

NTF's members also maintain their unwavering belief that the federal standard for labeling poultry as "fresh" and "frozen" must pre-empt any and all state standards. To do otherwise is to invite economic chaos. Here's why:

- The California law -- regardless of the intentions of its supporters -- serves to create an interstate trade barrier and gives California processors an enormous and unfair marketing advantage over their competitors. Because it is extremely difficult to ship poultry over long distances at temperatures above 25 degrees, the end result of the law is that virtually no turkey or other poultry product processed outside California can be sold in California as "fresh."

- The California law will deny consumers in that state the benefit of free-market competition. If California is allowed to use its own standard, California processors will be able set the price for "fresh" poultry products without fear of being undercut by market competition.

- California's own law governing retail labeling of poultry is not materially different

than the current USDA policy. Remember, California law still allows retailers to purchase turkeys labeled "fresh" at the wholesale level and then chill them to 5 degrees indefinitely without changing the "fresh" label.

Simply put, USDA should not allow -- and Congress should not condone -- the practice of erecting interstate trade barriers. If the California law stands, what is to stop other states from following suit? Soon, Pennsylvania could enact a law that effectively prevents the sale of New York poultry within its borders. State after state could follow suit. Even California itself could find markets in Hawaii, Nevada, Utah and Oregon cut off by similar legislation.

Conclusion

NTF finds it unfortunate that this issue still is not resolved. We are grateful, though, to the subcommittees for giving us the opportunity to testify.

This whole issue can be resolved if USDA conducts the research necessary to establish a true standard for differentiating between "fresh" and "frozen" poultry and then sets clear, national labeling guidelines through the rule-making process.

Until that new definition is developed, we urge the agency to maintain the existing definition of "frozen" and to apply it uniformly throughout the United States.

Thank you again for the opportunity to testify. I will be happy to answer any questions.

Mr. TOWNS. Thank you very much, Mr. Fanella, and also Dr. May and Mr. Mattos. Thank you for your testimony.

Let me begin by saying I would like to address this question to all three of you. Are you aware of how the Food and Drug Administration defines "fresh"?

Dr. MAY. I heard the definition the lady gave today. I am not absolutely certain of what they say, no.

Mr. MATTOS. I'm not aware of it.

Mr. TOWNS. Mr. Fanella.

Mr. FANELLA. My only understanding is that it is above zero degrees.

Mr. TOWNS. Pardon?

Mr. FANELLA. A product above zero degrees can be labeled as fresh, and that is my only understanding.

Mr. TOWNS. That is correct.

As I asked earlier, is there any scientific rationale for having two definitions of "fresh," one for foods regulated by the Food and Drug Administration and one for meat and poultry regulated by USDA? Is there any reason for that? Would you know of any reason for it?

Dr. MAY. Well, there might be in terms of what temperature microbial growth stops on different products. You might have a difference in fish than chicken or red meat product or something of that kind.

Mr. FANELLA. Mr. Chairman, I would have to really reiterate that theme, I guess, because different products could have different standards for freezing.

For instance—well, I can't give you a for instance, but if you look at a turkey that was chilled down to 22 degrees, it might under the definitions—the premise today that if it is under 26, it is frozen. You might think it is frozen, but if you take a 22-degree turkey, you will be able to put your thumbprint into it. You could also probably with a thermometer by hand, and if it was supposedly a rock solid bird at 22, 23 degrees, you wouldn't be able to do that.

So I think if you look at turkeys or broilers or other different products, I think there could be some basis for some differences. But I think what would underscore that premise would be the need for doing some scientific research and get some scientific basis for determining what that point—what those levels are.

Mr. TOWNS. All right.

Mr. MATTOS. We believe that you do have the scientific information and you also have the consumer information.

From what I have heard here today, you know, most of the panel here is interested in consumer perception and thanks to the California Poultry Federation you have that data not only from a California study but a recent study that was brought to you today, a nationwide consumer study about freshness. The scientific data, we believe FSIS accomplished in 1988. We also have the results from Cornell University, and University of California experts have also shown and told us what they believe is fresh and what they believe is frozen.

You know, from what I have heard here so far, it appears that in order to ship the chicken to California—and our studies show that you can get it there fresh; the technology is available—in order to get it to California, national companies say they need to

freeze it, and that makes it right to call it fresh, and we just don't believe that is the case.

Mr. TOWNS. Let me switch to Dr. May. Were you one of the poultry industry representatives that met with former Agriculture Secretary Richard Lyng in 1988 on policy memo 022B?

Dr. MAY. Yes, sir.

Mr. TOWNS. How many times did you meet with the Secretary on the issue?

Dr. MAY. I can recall one time for sure. If there were more, Mr. Chairman, I don't know. I wouldn't want to be held accountable for that. I know I met with him one time.

Mr. TOWNS. Did you meet with other USDA officials?

Dr. MAY. I'm sure that I probably did. I don't recall those——

Mr. TOWNS. Who?

Dr. MAY. I don't know. Possibly Dr. Crawford or some of his staff to give them our opinion on this particular issue.

Mr. TOWNS. So you advocated that 022B should be rescinded?

Dr. MAY. We advocated yes, on scientific grounds that—the same thing that I've told you today—that as long as bacteria grow on a product and cause spoilage of it, it's a fresh product. If you freeze a product, it will not spoil from microbial growth, and so it should be a temperature there, and to arbitrarily pick a figure like 26, that particular thing came up at that time because—the same reason that we have now, a particular individual in the industry or a group of individuals in the industry were trying to gain an advantage over others, and they sought the Government to try to help them get that advantage rather than free marketplace competition. It was not a consumer issue at that time.

Mr. TOWNS. Were you satisfied with 022C? Were you happy with that?

Dr. MAY. It's all right. I have no problem with the Department now looking into some different definition, but I would have personally a very serious problem with them picking a temperature as high as the one in California law because it just doesn't make sense. To me, if a product is frozen, you should not have bacterial growth on it that limits it shelf life.

Mr. TOWNS. All right.

Let me just—before my time runs out, let me just go to you, Mr. Fanella.

Thank you very much, Dr. May.

Your written statement mentioned that your executive committee recognized that consumers might be confused by a definition that allowed a turkey chilled to 1 degree to be labeled as fresh. Did you conduct the consumer survey for this information?

Mr. FANELLA. I'm not aware that we have at that time, Mr. Chairman. I would like to—I would like to point out, if I could that, there is certainly a very large difference between zero degrees and 26 degrees in that—in the realm of temperature at which point a bird should be determined fresh or frozen. We have some concern about transport of turkey at 26 degrees because we think that you hit the safety margin in terms of product safety.

I might like to also point out that it has been general industry practice today in the turkey industry that fresh birds are normally shipped somewhere about 20, 25 degrees and not down to about the

2, 3, or 5 degree level, and I make that point because I think there is a real differentiation between the discussion of a—frozen poultry at 2 degrees and 26 degrees, and I raise that issue because I think that is the reason why we need some scientific work done, conducted to determine at what point that bird truly is indeed frozen.

I have got to be careful I don't speak a little bit out of my competence in my next comment, but my understanding is that bacterial growth needs free liquid—water in a free liquid state in order to continue to grow, and so I have difficulty seeing how bacteria could continue to grow if that bird is frozen at 25 degrees or 26 or—excuse me—you know, at a certain level in there. So I think the scientific research is needed to help differentiate at what level that bird truly is frozen.

I know Dr. Les Crawford mentioned earlier that that work has been done, but I am not aware of it, and I think if that work could be presented that certainly would be helpful.

Mr. TOWNS. All right. Let me thank you very much for your testimony.

At this time I yield to Congressman Condit.

Mr. CONDIT. Thank you, Mr. Chairman, and I do want to thank all of the witnesses here on this panel for your patience. You have been here all morning, and I know that, and I appreciate you being here very much.

Dr. May, you mentioned the California law being too high. I'm curious about this picture of the shipping box I showed Secretary Rominger. Why does Tyson's box say that freezing temperature of poultry is 28 to 38 degrees but your testimony suggests it is not completely frozen until it reaches zero?

Dr. MAY. I have absolutely no idea why they do that, and my testimony says that—you know, the current law says zero. If I had to pick scientifically some place, I would say probably 14, 15 degrees, because that is where bacterial growth stops.

Mr. CONDIT. So you have no reason—you can't think of any reason why they are doing this?

Dr. MAY. I have no idea why they have a label that says that.

Mr. CONDIT. For all the panel, I would like to hear each of your thoughts on the possible creation of a new classification of poultry product labeled such as "fresh frozen" to represent zero to 26 degree range. Can I get your comments about that?

Dr. MAY. I would not be in favor of that because it is not frozen as long as it has a limited shelf life and it is going to spoil from bacterial growth. If you wanted to lower that to between zero and 15 degrees, I would be—that would be all right with me.

There is currently a regulation, though, that says—defines fresh frozen chicken or meat, and it specifies a time period. It has to be frozen to below zero within a specific time period, I think 24 or 48 hours. So you would have change that too. It would be another change in the definition.

Mr. CONDIT. Mr. Mattos.

Mr. MATTOS. Well, if the USDA refuses to act on this issue, as they have since 1988, and we continue saying we want to study the issue even though the studies are available and the information is there, and we have the consumer studies in place. If that is truly the case, then yes, we had better have a fresh frozen category. We

had better have zero to 25 as fresh frozen or frozen or whatever you want to call it, because our studies show that the actual bacteria growth that is harmful to humans stops when it gets to 32. If you look at all our testimony in court, I think the USDA would have wide open eyes at why Tyson does this, because everyone we deposed says fresh is 26 to 28 degrees.

All you have to do is go to each company one by one, and they'll dispute everything we have been hearing from the different organizations, and we have got all that in testimony. I think we need to get on with the issue, we need to go to rulemaking right away; we don't need to study the issue any longer.

Mr. CONDIT. Mr. Fanella, do you have any——

Mr. FANELLA. Yes, as my testimony supported, NTF certainly feels that we need to relook at the issue at USDA. However, I guess the concern I have was, if you add a third level classification, my first reaction is, it would—might tend to add more confusion to what is out there in the labeling issue than what we have had in the past.

Mr. CONDIT. Dr. May responded to the chairman's question a while ago about the meetings with Secretary Lyng at the time. Could each of you describe for me by either first or secondhand knowledge your recollections of the meetings with Secretary Lyng and Administrator Crawford in 1988? Does anyone here other than Dr. May have any recollection to that at all?

Mr. FANELLA. I was not part of that.

Mr. MATTOS. No. The only recollection or information I have is, when we decided to put the California law into existence we used that information.

Mr. CONDIT. Mr. Fanella, the review that the FSIS undertook in 1988 and 1989 seems to be fairly exhaustive. The NTF obviously feels that this review was inadequate to make a sound decision on the freshness issue. What was wrong with the previous review, or what did it lack?

Mr. FANELLA. I guess, Congressman, our concern was that—that we recognized to some degree that a consumer would pick up a bird at the minimal level, 2, 3, degrees and it certainly would feel very hard, that that could lend it some confusion. So the executive committee in 1991 did take a position in support of reevaluating or supporting USDA in any efforts that it would undertake to review the fresh frozen issue, and we just felt that was appropriate.

The concern we had is, we are certainly not convinced. We have seen no scientific data, to our knowledge anyway, that says 26 degrees is the proper temperature. Bacteria will still continue to grow down to about 14 to 15, and it seems to us that food safety is paramount, and when you start looking at fresh frozen issues, I guess our view was that—that's a real concern for us.

So the temperature may not have to be zero degrees, but we certainly don't think it needs to be as high as 16; there is some midpoint that is probably more appropriate.

Mr. CONDIT. Thank you.

Mr. Mattos, is it correct to say that consumers not only do not know if a product has been previously frozen but they do not know when it was packaged?

Mr. MATTOS. Right, they don't know because they don't have any information that tells them how to find out.

Mr. CONDIT. Once again to Mr. Mattos: Is there a limit to how far a nonfrozen poultry product can be shipped and still retain its freshness and be safe for consumption?

Mr. MATTOS. A limit to how far?

Mr. CONDIT. How far a nonfrozen poultry product can be shipped and still retain its freshness and be safe for consumption?

Mr. MATTOS. I don't think there is a limit to how far. It is probably how long it takes if they are using a technologically advanced system, and our deposition showed that these companies tell us they can ship 26 to 28 degrees right across the United States and get it to California in plenty of time and still call it fresh, that they do it and they can do it.

Mr. CONDIT. I have one last question for all of you. Have any of you been involved in consulting with the USDA in its current review of the freshness labeling, or were you consultants prior to its announcement? If so, could you describe the nature of your contract, or your contact?

Mr. FANELLA. I have not, Congressman.

Dr. MAY. I have not.

Mr. CONDIT. Thank you, Mr. Chairman, and I yield back the balance of my time.

Mr. TOWNS. Thank you very much.

At this time I yield to Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

Mr.—Dr. May, excuse me. Dr. May, I agree with you that in ordinary usage the word "fresh" can have several different meanings. For example, if you ask someone in your household, "Is the milk still fresh?", I don't think they mean, "Has it frozen?", you know, I think they mean, "Has it gone to a situation where it is not drinkable?"

But in this we are talking about one particular aspect of the word "fresh" here. We're talking about the labeling of poultry as fresh in the meat counter of food stores where the public buys their meat, poultry and otherwise.

Now in that context, if the members of the public are looking for a label called "fresh," what is it you think they are looking for?

Dr. MAY. Congressman, the temperatures that we are talking about—and we're not talking about bringing product down close to zero degrees. Nobody in the industry does that. It would be very expensive to do it. We do it only if we intend to freeze the product to zero and below. But we do ship product sometime in the area of 20 to 28 degrees, and that product has been shipped all over the United States for the last 25 years. It is obvious that consumers find it an acceptable product. They have not been confused about it.

They did not bring up this issue. Every time this issue has ever arisen in the past, it has been specifically one or two people or someone in the industry wanting to get an edge competitively, to try to have an edge where they can sell a product with the help of a regulation.

Mr. SCHIFF. You will forgive me, Dr. May, but you didn't answer my question. My question was, when the public is looking for the

word "fresh" on poultry at the meat counter, what do you think in that context they mean by the word "fresh"?

Dr. MAY. I think they want the product that is the same as the milk you talked about. When they open it up, they do not want to smell it, they want it to have a nice aroma, and they want it to taste good when they cook it and eat it.

Mr. SCHIFF. So you think the public looks for the fresh meat counter as opposed to the unfresh meat counter?

Dr. MAY. You bet. If you really want to upset a consumer, you just let a package of chicken spoil somewhere.

Mr. SCHIFF. Do you think the public believes that there's two counters, one for the counter for fresh poultry like you've described it and one counter for the not fresh poultry as you have described it?

Dr. MAY. No, sir, because we put open code dates on all of our packages to tell people when we expect them—you know, sale date on the product, and they look for that so they'll know, and this product is the same product that we are talking about here, and some of it is below 26 degrees, but it has an open code date and it has a limited shelf life.

Mr. SCHIFF. Don't you think that at the meat counter the public assumes that all the meat is fresh in the sense of having a good aroma and being consumable——

Dr. MAY. Yes.

Mr. SCHIFF [continuing]. And that when they—when they look for the word "fresh" in this context, they mean not frozen? Don't you think that is what the public believes?

Dr. MAY. No, sir, I don't. I have no reason to believe that they are thinking about frozen at all when they look at the product. They have an expectation that it is fresh, that it is going to smell good, look good, taste good, and have a reasonable shelf life.

Mr. SCHIFF. Well, that means then that they think that any item of poultry marked "fresh" is not going to look good, smell good, and taste good. That is what they would think, according to your analysis.

Dr. MAY. You asked me what I thought they thought. I've explained to you what I think they think. I am not an expert on consumers and what they think, but I know that we have sold literally billions and billions and billions of pounds of product over 25 years with the current systems without consumer complaints or upset consumers.

Mr. SCHIFF. Nobody is suggesting here you cannot continue to sell that product. The only issue here is, should that product be labeled as fresh, and I would have to say that, with respect to Dr. May, I think consumers mean not frozen when they see "fresh" at the meat counter, and I think that all of this discussion of food safety and bacteria has relevance, I am not putting down food safety, I just don't think it is relevant to what we are talking about here.

I yield back, Mr. Chairman.

Mr. TOWNS. Thank you very much.

At this time I yield to Congressman Peterson.

Mr. PETERSON. Thank you, Mr. Chairman.

Could any of you comment on how many States have a regulation like this? Do any of you know?

Mr. MATTOS. I can comment on that. There's about three States with a fresh law right now, and there's also other States with labeling requirements on poultry saying that they have to be labeled with point of origin information. None of those States have ever been challenged by the USDA. Obviously, we have a big market for poultry and so they have chosen to attack us.

Mr. PETERSON. You know, I am a little bit troubled by this, the word "fresh." I also believe the consumers don't necessarily think that when it says "fresh" it means it was never frozen. I mean I don't—that's not what I think about it, and I think there's a lot of people like myself.

So why, when you were doing this law, why didn't you have a label saying "never frozen" instead of "fresh"? That would seem to me to be a lot more acceptable term descriptive in terminology of what is actually the situation.

Mr. MATTOS. The consumers absolutely believe that it is never frozen, according to all of our research, and we have very, very good data with like 3 to 5 percent statistical sampling error, and it tells you that 80 percent of the consumers never believed that the poultry was ever frozen at all when they purchased it fresh.

Consumers don't have enough information to make the decisions that Dr. May and the others are talking about. They assume that their fresh poultry has never been frozen. Sure, when they go to the supermarket they figure they are buying a fresh product, but they don't have enough information to know that that product was ever down to 5 degrees because we never told them. If we would tell them that fresh poultry was previously frozen—and we have told them in California—then they care. All of our studies confirm this—a California research study and a national study. We thought we had better do a national study with a research firm that you have used before that shows us that the majority of consumers believe we are right and they don't believe the product has ever been frozen. When they know it has been frozen and still labeled "fresh," they are absolutely astounded, and that is, I think, why we have Consumers Union, Consumers Action League, Public Voice, Consumer Federation of America supporting us. That is why we have all the consumers groups on our side, because we are right on this issue.

Mr. PETERSON. Well, it is still 80 percent, I guess. Again, are you against the idea of having the word "never frozen" instead? I mean isn't it really a marketing issue? I mean far more likely to buy something that says it's fresh?

Mr. MATTOS. I think the Broiler Council and—and some of the other groups are making it a marketing issue. They're making it a marketing issue.

Mr. PETERSON. No, you are making it a marking issue. I mean you have figured out a way that you can get more money for your product.

Mr. MATTOS. No. We have always sold fresh product; 98 percent of our chicken is fresh in California. We have never had to deal with a frozen product because we don't sell frozen chicken unless we have to export it somewhere, to Mexico or somewhere, that they

want to buy leg quarters, et cetera, which is only about 2 percent of our market. But we were finding that consumers were being misled. As I spoke throughout the State——

Mr. PETERSON. But you had until this morning apparently or probably even yet today a law on your books that says that at the retail level they can freeze it down to 5 degrees.

Mr. MATTOS. Well that's—that part——

Mr. PETERSON. So if that kind of——

Mr. MATTOS. The reason for that—let me explain that the National Turkey Federation, I think, was very—very good to find that out. When I worked on that law, I honestly did not know that that was in the health and safety code. So when it passed, there was a 5 degree law for the retailer that no one ever looked at, but the Turkey Federation had some good people working for them, and they found that in our law.

However, we do have a new law today signed by the Governor, that is a whole new fresh law, that answers all four issues the judge was concerned with. One was that, one was the issue of severability, and one was the issue of the consumer's right to know. Yes, you are right, that was a mistake on our part, but now it is corrected.

Mr. PETERSON. Mr. Chairman, it just seems to me that it points out, you know, the problems with all of this, that apparently this was going on and nobody was complaining too much about it if it didn't get noticed and it didn't get changed until the Turkey Federation brought it up.

Mr. MATTOS. No, but you see, our law was never enacted. You remember, we were sued, so we never got to enact the law, so that 5 degree was never enacted anyway, and so now, when this new law takes effect tomorrow, we will have to see what happens.

Mr. PETERSON. Well, Mr. Chairman, I just think that a lot of this has to do with marketing. I mean California rice people are upset with my Indians because we require them to say that their wild rice is not real wild rice grown on the Indian reservations but it is actually paddy rice from California, and they have been challenging us because we get more money for our rice than they do.

So we all know what this is about. I think there is a good argument in all of this to look at the whole thing nationwide and come up with something that we can all live with across the Nation, and that is the solution to this in, in my opinion, rather than to sit around and debate about fresh and never frozen and all this sort of thing.

So thank you, Mr. Chairman, for the time. I appreciate it.

Mr. TOWNS. Thank you very much, and let me thank you for your testimony. At this time I ask unanimous consent to hold the record open for 10 days to allow other interested parties to submit written statements for the record on the issue of fresh versus frozen poultry.

What we have heard here today is astounding: the U.S. Department of Agriculture cares more about the industry it is supposed to regulate than about the consumers it is supposed to protect. USDA's policy on fresh poultry is misguided and needs to be revised based on sound science and thorough process open to the public. We will continue to look at this issue until it is resolved.

This hearing is adjourned.

[Whereupon, at 2:04 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

REINVENTING THE FEDERAL FOOD SAFETY SYSTEM

(Chemical Residues and Contaminants in Food)

WEDNESDAY, SEPTEMBER 28, 1994

HOUSE OF REPRESENTATIVES,
HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2247, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the subcommittee) presiding.

Present: Representatives Edolphus Towns, Steven Schiff, John L. Mica, Rob Portman, and Bernard Sanders.

Also present: William M. Layden, professional staff member; Martine M. DiCroce, clerk; and Martha B. Morgan, minority professional staff, Committee on Government Operations.

Mr. TOWNS. The subcommittee will come to order.

Today, the subcommittee continues its review of the Vice President's proposal on reinventing Federal food safety efforts.

The subcommittee's hearings have revealed that USDA and FDA are not adequately protecting consumers from microbial contamination of food, the major cause of foodborne illness in the United States.

Today, we will review the Federal Government's programs to ensure that the Nation's food supply is not being poisoned with unsafe chemical residues and industrial and environmental contaminants.

We will hear testimony from the General Accounting Office on two reports prepared at the subcommittee's request. One report analyzes USDA's efforts to monitor chemical residues and contaminants in meat and poultry. The second report examines the overall Federal structure and programs for monitoring chemical residues and contaminants in all food. We will also hear from USDA, FDA, and EPA.

Fear about unsafe pesticides, animal drugs and environmental contaminants in our food, especially our children's food, such as dioxin and lead, continues to be one of the major public health issues of our time. The public expects to be protected from unsafe chemical residues and contaminants in their food. The question before this subcommittee is: How well is the Federal Government doing the job?

The answer is frightening. As GAO will testify, the Federal Government's existing approach for ensuring that the U.S. food supply does not contain unsafe chemical residues and contaminants is fundamentally flawed. The existing screen is not only letting in gnats, it is letting in bulldozers. And the safety problems of imported food are even worse.

The Federal Government simply cannot test much of the food supply for many of the residues and contaminants that are in our food because of limitations in technology and resources, and limitations in our knowledge about what our food is exposed to.

Even when the government tests and finds violations, contaminated food often reaches consumers before the test results are back from the lab. And then, the Federal Government prosecutes only a minuscule number of violators.

In short, the Federal Government's current approach is to chase problems after they occur. This is like closing the barn door after the animals have escaped. It is ineffective and costly. It does not deter future violations. And most importantly, it does not prevent problems from occurring.

That is why over 110 million boxes of cereal, adulterated with an unapproved pesticide, escaped detection by the Federal Government for over 1 year and reached millions of consumers. Fortunately, FDA and EPA have determined that there was not a safety problem and the company appears to have responded to this. However, it is pretty clear that the system is badly broken and needs to be fixed.

The worst part about the situation is that the Federal Government has known for some time that its current approach is flawed. The officials testifying today inherited these defective programs. Our focus is not to lay blame today. Our focus is to seek solutions. We need solutions to these problems.

The Federal Government needs a new approach to monitor unsafe chemical residues and contaminants in food. And we need it now. We cannot afford the luxury of waiting.

At this time I yield to the ranking member of the subcommittee, Mr. Schiff from Albuquerque, NM.

Mr. SCHIFF. Thank you, Mr. Chairman.

Mr. Chairman, I have a couple of things I would like to say briefly. The first is to commend you on continuing this series of hearings which we have had on the safety of the food supply to American consumers.

I believe that our first hearing was on the E. coli bacteria contamination last November. And I read just recently, I believe, in the East Coast of a recent breakout of E. coli sicknesses which shows that we have picked a subject that is very current and very real and very much in need of congressional study.

Second of all, I want to say that the more I have studied this issue, along with you, the more I am convinced that we do need, as the Congress, to centralize food safety inspection into one agency. I think one of the problems is that it is spread out certainly at least to two different departments, and I think when you look at the whole list of different players, we will see that food safety responsibility actually extends into several Federal departments.

I am convinced that we would be more effective in monitoring the food supply safety in this country if there was one single agency that was responsible for that task.

Now, the problem, of course, is identifying which agency, if we were to use a current agency to be given that responsibility, or if we were to create a new agency, where would that be placed in terms of Federal responsibility? That remains a very real issue. But I think the policy of centering food safety in one agency to me is glaringly important and something that we should make as our goal.

I would take as an example the reference you made to a contamination of a cereal. I believe I am familiar with what happened in that situation. And it should be pointed out that what actually happened is that a contractor being used by a cereal producer without authorization—in fact, absolutely against the policy of the cereal manufacturer, used a chemical that was never authorized, should never have been used in the first place. And this was unknown to the cereal company and they did everything possible to rectify it once they found out what happened.

But the issue is not the cereal company. The issue is, how long did it take the system to discover the fact that an individual was contaminating a particular cereal before it was discovered and before this particular batch was taken off to the market? That is the issue.

And I think if there was one agency responsible for all Federal food service inspections, that we would have seen a prompter detection of that problem.

Thank you, Mr. Chairman. I yield back.

Mr. TOWNS. Let me thank you too for your very thoughtful statement. And I agree with you that safety is really the issue. And it is what we are dealing with this morning.

At this time I would like to call on Mr. Harman, Director of Food and Agriculture Issues from the GAO. And may I ask that you please introduce the staff members that might be providing testimony this morning.

It is the custom of the Government Operations Committee to ask that all the witnesses who testify before the committee to be sworn in.

[Witnesses sworn.]

Mr. TOWNS. Let the record reflect that the witnesses have answered in the affirmative.

Let me also say that your entire statement will be included in the record, and if you would summarize it in 5 minutes that would allow time for the Members to raise certain questions with you. We would appreciate it.

STATEMENT OF JOHN W. HARMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY EDWARD ZADJURA, ASSISTANT DIRECTOR

Mr. HARMAN. Mr. Chairman, I would like to introduce Ed Zadjura. He has been responsible for our food safety work as an Assistant Director for the last 5 or 6 years. We are pleased to partici-

pate in this hearing, which is a continuation, as you mentioned, of the subcommittee's efforts to improve the effectiveness of the Federal food safety system.

We have been for some time calling for fundamental changes in that system, particularly in its ability to protect the food supply from microbial hazards. And today we will discuss the system's ability to protect against unsafe chemical residues and environmental contaminants. My comments are based on the two reports that you talked about in your opening comments.

First, regarding the National Residue Program, the program has weaknesses in testing and sampling as well as in the support it receives from other agencies. For example, FSIS, which is the agency that carries out that program, could not ensure that compounds presenting the greatest risk have been identified and are being tested for under the program.

There are also flaws in the NRP sampling methodology which may bias the results. And finally, because NRP testing focuses on domestic compounds of concern, it is of limited value in determining whether imported meat and poultry contains unapproved or banned drugs or pesticides.

As for the support FSIS receives from other agencies, EPA and FDA may not be able to provide FSIS with the most current information on chemical risks and tolerance. Further, because of limited resources, FDA investigated only about 20 percent of the over 21,000 residue violations referred to it by FSIS from 1989 to 1992.

Of the violations investigated, about 9 percent resulted in regulatory action against violators, mostly in the form of warning letters that carried no penalty, and there was one prosecution that resulted from these investigations.

The problems that we have identified with this program are not unique. They exemplify problems we and others have been describing for the past two decades for many Federal programs that monitor chemicals and domestic and imported foods.

While the Federal agencies have taken steps to address criticisms, they could not by themselves overcome five systemic and structural weaknesses that are responsible for the continuation of these problems because some of these weaknesses are the result of legislation and the design of the Federal food safety system. Successful corrective action will depend on congressional action.

I will briefly talk about each one of the five weaknesses that we describe in the report. The fragmentation of responsibility among the multiple agencies results in inefficiencies and gaps in Federal monitoring activity. For example, among EPA, FDA, and USDA, there is little agreement on the data that should be collected the methods for analyzing these data and ultimately the results of the data analyzed.

Consequently, the agencies may not reach the same conclusions on the level of risk posed by a particular chemical and the level of needed regulation. And chemicals posing similar risk may be regulated differently under different laws.

We found that the Federal food safety laws have resulted in different standards for chemicals that do not generally require the agencies to regularly reevaluate chemicals approved in the past

against current scientific standards and do not specifically address the critical risk posed by environmental contaminants in food.

In addition, unapproved chemical use has become a routine practice as a result of Federal regulation and policy that allow the use of unapproved pesticides and animal drugs to address emergency situations.

Third, Federal agencies rely on programs to detect unsafe chemicals in food rather than preventing these problems from developing. The basic Federal approach to ensuring food safety, end product testing, is not only resource intensive but ultimately ineffective in preventing contamination from occurring.

New approaches to ensure food safety such as the hazard analysis and critical control point, or HACCP, approach recognize these difficulties and seek to build safeguards into food production.

Fourth, agencies lack strong enforcement authorities to adequately deter or penalize violators. For example, FDA which is the primary enforcing agency for food violations, does not always act on violations referred by other agencies because of a lack of resources and other competing priorities. Moreover, FDA lacks the authority to detain violative products and to assess civil penalties.

Finally, similar problems exist for imported foods where the United States has even less control. Weaknesses in the U.S. system result in gaps in the monitoring of imported foods for several reasons.

First, FDA's inspection resources just cannot keep pace with the growing volume of imported foods. Second, some imported foods may not be being tested for compounds that are used in exporting countries but that are not approved for use in the United States. And third, as a result of the weaknesses in its regulatory authorities, FDA in some instances has not been able to prevent the distribution of contaminated imported products to U.S. consumers.

We do make a number of recommendations in the report. There are two key ones in these reports. One has to do with moving the process more to prevention as opposed to end product testing and the other one has to do with the creation of a single food safety agency which we have been advocating for several years now.

That completes my summary, Mr. Chairman. We would be pleased to answer any questions that you or Mr. Schiff may have.

[The prepared statement of Mr. Harman follows:]

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Operations, House of Representatives

For Release on Delivery
Expected at
9:45 a.m. EDT
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FOOD SAFETY

Fundamental Changes Needed to Improve Monitoring of Unsafe Chemicals in Food

John W. Harman, Director
Food and Agriculture Issues,
Resources, Community, and
Economic Development Division

GAO/T-RCED-94-311

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to participate in this hearing on the need to improve the effectiveness of the federal food safety system. In previous reports and testimonies, we have stated that fundamental changes are needed to this system to better protect the nation's food supply from microbiological hazards.[1] Today, we will discuss the federal government's system for ensuring that the food supply does not contain unsafe chemical residues and environmental contaminants. Our testimony is based on two reports requested by this Subcommittee, which are being released today--one analyzes the U.S. Department of Agriculture's National Residue Program (NRP) for monitoring chemical residues in meat and poultry, and the second examines the overall federal structure and systems for controlling chemicals in all foods.[2]

In summary, our recent work demonstrates that there are improvements needed in the approach used to monitor chemicals in the food supply. Specifically we found the following:

-- The NRP has weaknesses in testing and sampling, as well as in the support it receives from regulatory agencies. These weaknesses could be overcome if certain processes were strengthened. However, any improvements made would not address the basic problem with the program: reliance on detecting residues at the end of the production process to ensure safety rather than on preventing these problems from developing.

-- We have identified five basic weaknesses in the structure and systems for monitoring chemicals in food. First, fragmentation of responsibility among multiple agencies results in inefficiencies and gaps in federal monitoring activities. Second, chemicals posing similar risks may be regulated differently under different laws. Third, federal

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[1]Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994); Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110, May 19, 1994); Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/T-RCED-94-189, Apr. 19, 1994); Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993); Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

[2]Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 26, 1994) and Food Safety: Changes Needed to Minimize Unsafe Chemical Residues in Food (GAO/RCED-94-192, Sept. 26, 1994).

agencies rely on programs to detect unsafe chemicals in food rather than preventing these problems from developing. Fourth, agencies lack strong enforcement authorities to adequately deter or penalize violators. Fifth, similar problems exist for imported foods, over which the United States has even less control.

Before we discuss the results of our work in more detail, some brief background information may be useful.

BACKGROUND

Potentially unsafe chemicals can enter the food supply from chemicals used during food production as well as from the environment. Before they can be used legally in the United States, pesticides, animal drugs and chemical additives must be approved by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), respectively. If these chemicals leave residues, the cognizant agency is responsible for establishing a tolerance level--the amount of residues that can legally remain in or on raw and processed foods.[3] Environmental contaminants, unlike chemical residues, are not intentionally used in food production but enter the food supply through their occurrence in the environment naturally or through air, water, and soil pollution.

Although chemical hazards are generally ranked as less important than microbiological hazards as a public health issue, the long-term and chronic effects of these hazards are an important public health concern. The U.S. Department of Agriculture (USDA) monitors chemical residues and environmental contaminants in meat, poultry, and some egg products, and FDA monitors them in all other food products.

USDA's Food Safety and Inspection Service (FSIS) uses the NRP to detect, measure, and reduce potentially harmful chemicals in meat and poultry products. Under the program, FSIS samples and analyzes domestic and imported meat and poultry for unsafe chemicals at the slaughterhouse. FSIS refers violations it identifies to EPA, FDA, and/or the states, as appropriate for follow-up and regulatory action.

PROBLEMS WITH THE NATIONAL RESIDUE PROGRAM

The NRP has basic flaws in the choice of chemicals tested and the methodology used to select samples for testing. In addition, the program suffers from limited support from EPA and FDA to identify potentially hazardous chemicals and to prosecute

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[3]Some chemicals may have a tolerance level of zero, and therefore no residues of the chemicals are allowed in food, while others may not require a tolerance.

violations.

NRP's Test Results Are Not as Useful as They Should Be

The NRP's test results are not as useful as they should be in determining whether the meat and poultry supply does or does not contain potentially unsafe chemicals for the following reasons:

-- FSIS cannot ensure that compounds presenting the greatest risk have been identified and are being tested for under the program. This occurs because (1) FSIS has ranked (prioritized) only about one-third of the 367 compounds it has identified as being of potential concern for meat and poultry and (2) test methods have not been developed for all compounds. Furthermore, only 24 of the 56 compounds tested in 1992 were high priority. Although FSIS plans to devote more resources to ranking additional compounds and developing more test methods, these tasks will take many years to complete.

-- Flaws in the NRP's sampling methodology may bias the program's testing results. For example, we found that FSIS does not (1) consistently follow random sampling procedures, (2) adjust its sampling of some species to compensate for climatic/geographic and seasonal changes in slaughter rates and animal drug use, and (3) consistently sample different animal species and chemical compounds.

-- Because the NRP's testing focuses on domestic compounds of concern, it is of limited value in determining whether imported meat and poultry contains animal drugs or pesticides not approved or banned for use in the United States. The potential for hazardous residues in imported products is a concern for two reasons: (1) Certain exporting countries have reported finding high incidents of heavy metal residues in excess of their own domestic standards, and (2) some countries may use animal drugs or pesticides not approved or banned in the United States. However, FSIS does not adjust its testing of imports to reflect these concerns.

Other Agencies Provide Limited Support to the Program

EPA and FDA cannot always provide the support the NRP needs to be effective, as the following examples show:

-- EPA and FDA may not be able to provide FSIS with the most current information on chemical risks and tolerances. EPA is in the process of reregistering pesticide products but may not complete this task until 2006, and FDA has not reevaluated all animal drugs approved in the past because of resource constraints.

-- Because of limited resources, FDA investigated only about 20 percent of the 21,439 residue violations referred to it by FSIS from 1989 through 1992. Of those violations investigated, only about 9 percent resulted in regulatory action against violators, mostly in the form of warning letters that carry no penalty. Only one prosecution resulted from these investigations.

FUNDAMENTAL CHANGES NEEDED IN THE FEDERAL FOOD SAFETY SYSTEM

The problems that we identified in the NRP are not unique. They exemplify problems GAO and others have been describing for the past two decades for many federal programs that monitor chemicals in domestic and imported foods. For example, FDA faces many of the same problems when monitoring pesticides in fruits and vegetables or environmental contaminants in fish products. While the federal agencies have taken steps to address criticisms, we believe they cannot, by themselves, overcome five systemic and structural weaknesses that are responsible for the continuation of these problems. Because some of these weaknesses are the result of legislation and the design of the federal food safety system, successful corrective actions will depend on congressional initiatives.

Fragmentation of Responsibility Impedes the Identification of Chemical Risks

Under the current federal food safety system, responsibilities are fragmented across many agencies. As a result, the system is characterized by inefficiencies and gaps in monitoring. Nowhere is this more apparent than in agencies' efforts to assess chemical risks. To control unsafe chemicals effectively, agencies need a large amount of human exposure and residue data to first assess the risks posed by a chemical. However, because responsibility for collecting these data is split among FDA, EPA, and USDA, there is often little agreement on the data that should be collected, the methods for analyzing these data, and, ultimately, the results of the data analyzed. Consequently, the agencies may not reach the same conclusions on the level of risk posed by a particular chemical and the level of needed regulation.

Problems in the Legal and Regulatory Structure Compromise Efforts to Reduce Risk

Even if agencies had reliable information to better control chemical risks, differences in the basic laws and regulations that govern chemicals in food do not support the agencies' efforts. For example, we found that federal food safety laws (1) have resulted in different standards for chemicals posing similar risks, (2) do not generally require the agencies to regularly reevaluate chemicals approved in the past against current scientific standards, and (3) do not specifically address the critical risk

posed by environmental contaminants in food. In addition, as a result of federal regulation and policy that allow the use of unapproved pesticides and animal drugs to address emergency situations, the use of unapproved chemicals has become a routine practice.

Increased Focus on Prevention Is a Better Approach

The basic federal approach to ensuring food safety--end-product testing--is not only resource-intensive but ultimately ineffective in preventing contamination from occurring. This approach requires an everincreasing amount of resources, both to keep pace with the commodity/chemical combinations of concern and to develop all the multiresidue tests needed to detect these residues. The problems in the NRP demonstrate the shortcomings of relying on end-product testing. Newer approaches to ensure food safety--such as the Hazard Analysis and Critical Control Point (HACCP) approach--recognize these difficulties and seek to build safeguards into food production. The HACCP approach generally integrates chemical prevention, detection, and control functions at critical points throughout the production process. Under this approach, end-product testing becomes a secondary rather than the primary method of ensuring that unsafe levels of chemical residues and environmental contaminants do not remain in food products. While the benefits of HACCP-based systems have been recognized for over 20 years, the federal government has made little progress in implementing such systems.

Limited Enforcement Authority Cannot Effectively Deter or Penalize Violators

Federal enforcement efforts do not provide the backup that is necessary to ensure compliance with federal food safety standards when violations occur. FDA, the primary enforcing agency for food violations, does not always act on violations referred by other agencies, as demonstrated by the problems we found in the NRP, because of a lack of resources and other competing priorities. Moreover, FDA has inadequate enforcement authorities and cannot effectively prevent the distribution of violative products to consumers or prevent future violations from occurring. This happens because FDA lacks the authority to detain violative products and to assess civil penalties. When FDA finds a potentially violative product, it must obtain a court order to seize the products. However, while FDA is obtaining the court order, potentially unsafe food may be shipped and sold to consumers. Similarly, FDA must rely on the Justice Department to pursue criminal action against violators because FDA does not have the authority to assess civil penalties. However, the number of cases pursued under criminal law is minuscule because this is a resource- and time-intensive activity. For example, of the over 21,000 drug residue violations reported to FDA, between 1989 and 1992, only 15 resulted in criminal action.

Similar Problems Exist With Imported Products

Finally, the problems we have identified in the domestic food safety system are also relevant for imported foods because federal agencies have even less control over the production of imported foods. U.S. agencies have no jurisdiction over food producers in exporting countries and therefore rely on the adequacy of exporting countries' food safety systems and/or U.S. inspecting and testing of imported products at the port of entry to ensure the safety of imported foods. However, not only are food safety systems in some exporting countries inadequate but also weaknesses in the U.S. system result in gaps in monitoring imported food for several reasons.

First, FDA's inspection resources cannot keep pace with the growing volume of imported food. Second, some imported products may not be tested for compounds that are used in exporting countries but are not approved for use in the United States because the agencies may have incomplete data on these chemicals, and/or because some of the testing focuses only on domestic compounds of concern. Third, as a result of weaknesses in its regulatory authorities, FDA, in some instances, has been unable to prevent the distribution of contaminated imported products to U.S. consumers. Although FDA has the authority to detain contaminated imports, it does not have the authority it needs to control and prevent the distribution of unsafe imports. For example, while meat and poultry can only be imported from countries that have food safety systems that have been reviewed and certified by USDA as being equivalent to the U.S. system, FDA must rely on voluntary agreements with foreign countries to ensure that imported products comply with U.S. standards. Similarly, as with domestic foods, FDA lacks civil penalty authority and must rely on another agency, in this case the Customs Service, to provide an economic deterrent to violators. However, because of poor coordination between the agencies, these damages are often not assessed.

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In summary, Mr. Chairman, as we have continually reported over the past 20 years, the federal system designed to ensure that food is free from unsafe levels of chemicals needs significant improvement. We believe a restructuring of the federal monitoring system for chemical residues and environmental contaminants in food is needed. Our most recent reports suggest that the Congress should take the following steps:

-- Enact a uniform set of food safety laws that include consistent standards for chemical residues and contaminants in food and provide federal agencies with the authorities needed to effectively carry out their oversight responsibilities.

-- Revise the nature of the federal government's role for ensuring food safety by moving it away from end-product testing to preventing contamination from occurring. End-product testing would take a secondary role to monitor the effectiveness of the prevention system.

-- Consider the feasibility of requiring that all food eligible for import to the United States--not just meat and poultry--be produced under equivalent food safety systems.

Mr. Chairman, this completes our prepared statement. We would be happy to respond to any questions.

(150637)

Mr. TOWNS. Thank you very much for your statement. Let me also, at this time, thank you for those two excellent reports.

Before I get to the specifics, let me make certain that we understand the big picture. Can the Federal Government test for all the hazardous chemical residues and contaminants that may be in our food?

Mr. HARMAN. No, Mr. Chairman, I am afraid not. And that is one of the flaws in the system. There are just too many.

Mr. TOWNS. If it finds a problem, can the Federal Government generally prevent the distribution of contaminated food if there is a problem?

Mr. HARMAN. Not as it exists right now, no.

Mr. TOWNS. Can the Federal Government effectively penalize violators and deter future residue violations if they find them?

Mr. HARMAN. No, Mr. Chairman. As we have said, we are calling for some improvements in that area, and I believe the administration for the most part agrees with us on that need.

Mr. TOWNS. Can the Federal Government effectively prevent residue and contamination problems from occurring, period?

Mr. HARMAN. No.

Mr. TOWNS. Is the current Federal approach to monitoring chemical residues and contaminants in food fundamentally flawed?

Mr. HARMAN. Yes, it is. And that is because we just rely too heavily on end product testing and not enough on prevention, basically.

Mr. TOWNS. Mr. Harman, what is the basis for GAO's findings?

Mr. HARMAN. Well, it involves some two decades worth of work that has been done by us and by others. We have brought up some of the work that forms the basis of these particular products that were issued today and you can see it is quite a few. We didn't bring them all, because I was just afraid of injuring my staff with additional weight that had to be brought up. But it is quite a bit of work. And our work was based on that, as well as updating what had been done.

Mr. TOWNS. On the basis of all of that work—and we are happy that you didn't injure your staff—is the existing Federal approach to monitoring chemical residues and contaminants in food adequately protecting consumers?

Mr. HARMAN. No, it is not. And I don't mean to infer that we have unsafe food out there. But given what the laws are intended to do, it is not doing that. And I am afraid to say, as you pointed out in your opening statement, that this system probably cannot do that—because you just cannot do the end product testing that is needed to give the consumers the kind of assurance that they are probably going to need to feel that the system is safe.

Mr. TOWNS. Your report states that USDA's residue program is flawed. How many chemical compounds has USDA ranked as high priority for testing?

Mr. HARMAN. There were 48.

Mr. TOWNS. How many of these high-priority compounds did USDA test for in 1992?

Mr. HARMAN. About 24.

Mr. TOWNS. Why didn't USDA test for the other 24 high-priority compounds?

Mr. HARMAN. Well, they didn't have methods for half those, 12 of them. And the other 12 simply were not tested because of other priorities or just lack of resources.

Mr. TOWNS. Could you provide an example of a high-priority compound that USDA did not test for?

Mr. HARMAN. I am going to let Ed answer that question. I think he probably can give you more detailed information than I may be able to.

Mr. ZADJURA. Yes, as a matter of fact, I could probably provide several. Furazolidone: Its use has been removed by FDA in this country, but it is still thought and believed to be in widespread worldwide use.

Clenbuterol: There have been over 1,000 significant adverse reactions in Europe. It hasn't been tested for in 1992 or 1993.

Chloramphenicol is believed to be used in cultured shrimp, of which we import up to 140 million pounds a year. It was not tested for in 1992 or 1993. Those would be three that I could think of.

Mr. TOWNS. Are there any health concerns with the drug furazolidone? Does it cause cancer?

Mr. ZADJURA. It is believed to be a carcinogen. That is one of the reasons its use was taken away in this country and there is no method to test for it.

Mr. TOWNS. Will you submit for the record a list of the high-priority compounds that USDA didn't test for in 1992?

Mr. ZADJURA. Yes.

[The list follows:]

HIGH-RANKED COMPOUNDS NOT TESTED FOR IN THE 1992 NATIONAL RESIDUE PROGRAM

	COMPOUND NAME	RANKING ASSIGNED UNDER FSIS' COMPOUND EVALUATION SYSTEM (CES)[1]	ACCEPTABLE TEST METHOD AVAILABLE
1.	Alachlor	A-2	No
2.	Ampicillin	B-2	Yes
3.	Ampicillin trihydrate	B-2	Yes
4.	Arsanilic acid	C-1	Yes
5.	Chloramphenicol	A-2	Yes
6.	Chloramphenicol palmitrate	A-2	Yes
7.	Chlorsulfuron	B-2	No
8.	2, 4,-D and metabolite	B-2	No
9.	Dalapon	A-3	No
10.	Dibutylin dilaurate	A-1	Yes
11.	0, 0,-Diethyl S-[2-(ethylthio) ethyl phosphorodithioate	A-2	No
12.	Dihydrostreptomycin	A-1	Yes
13.	Furazolidone	A-1	No
14.	Gentian violet	A-2	No
15.	Hygromycin B	A-3	Yes
16.	Methylene chloride	A-2	No
17.	Nitrofurazone	B-1	No
18.	Pentachlorophenol (PCP)	B-1	Yes
19.	Roxarsone	C-1	Yes
20.	Silvex	A-3	No
21.	Spectinomycin hydrochloride	B-2	Yes
22.	Sulfaquinoxaline	B-1	Yes
23.	2, 4, 5-T	A-3	No
24.	Thiram	A-2	No

[1]According to FSIS' criteria, compounds having CES rankings of A-1 through A-3, B-1, B-2, and C-1 are considered as "high priority" and are to be selected for NRP testing--or for test method development if an acceptable method of testing for the compound does not exist.

Mr. TOWNS. Your report presents some alarming data on imported meat. Let me just ask this question, then I will yield for Mr. Schiff's round. How much meat and poultry does the United States import?

Mr. HARMAN. Somewhere between 4 and 6 percent of our consumption is imported.

Mr. TOWNS. Your report states that USDA does not test imported meat for pesticides and animal drugs approved for use in foreign countries but not approved or banned in the United States. Can you provide some examples?

Mr. ZADJURA. I would primarily start off with the three I just gave you. Nitrofurazone, clenbuterol, chloramphenicol, there is also one called nitrofurazone, another animal drug that is used at least in some countries.

A couple of years ago the USDA Inspector General did a study and identified in just five countries, 175 unapproved animal drugs that those countries weren't testing for and we weren't either, and there are many other examples.

Mr. TOWNS. OK. I ask unanimous consent to enter into the record documents obtained by the subcommittee from FDA and USDA which show that nitrofurans, particularly furazolidone, clenbuterol and chloramphenicol are used world-wide on food-producing animals.

Without objection.

[The information referred to follows:]

COMMISSION OF THE EUROPEAN COMMUNITIES

SEC(93) 773

Brussels, 13 May 1993

REPORT ON THE ACTIVITIES OF THE COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS DURING 1991 AND 1992

(Commission Staff Working Paper)

ANNEX IV

MAXIMUM RESIDUE LIMITS ADOPTED BY THE COMMISSION FOLLOWING THE RECOMMENDATIONS OF THE CVMP

(Regulation (EEC) 2377/90EEC)

A Annex I is hereby replaced by the following

'ANNEX I

List of pharmacologically active substances for which maximum residue limits have been fixed

1 *Anti-infectious agents*

1.1 Chemotherapeutics

1.1.1 Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	All food producing species	100 µg/kg	Muscle, liver, kidney, fat	The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg

1.2 Antibiotics

1.2.1 Penicillins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.1.1 Benzylpenicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.2 Ampicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.3 Amoxicillin	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat	
			4 µg/kg	milk	
1.2.1.4 Oxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	
1.2.1.5 Cloxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	
1.2.1.6 Dicloxacillin	Parent drug	All food producing species	300 µg/kg	Muscle, liver, kidney, fat	
			30 µg/kg	milk	

2 *Antiparasitic agents*

2.1 Agents acting against endoparasites

2.1.1 Avermectins

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1 Ivermectin	H2B1a – metabolite	Bovine, ovine, porcine, equine	15 µg/kg 20 µg/kg	Liver fat	The MRLs for liver and fat apply to all four species mentioned'

B Annex III is hereby replaced by the following

ANNEX III

List of pharmacologically active substances used in veterinary medicinal products for which provisional maximum residue limits have been fixed

1 *Anti-infectious agents*

1.1 Chemotherapeutics

1.1.1. Sulfonamides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the sulfonamide group	Parent drug	Cattle, sheep, goats	100 µg/kg	milk	Provisional MRL expires on 1 January 1994 The combined total residues of all substances within the sulfonamide group should not exceed 100 µg/kg

1.1.2 Diamino pyrimidine derivates

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.2.1 Trimethoprim	Parent drug	All food producing species	50 µg/kg	Muscle, liver, kidney, fat milk	Provisional MRL expires on 1 January 1996

1.1.3 Nitrofurans

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the nitrofuran group	All residues with intact 5-nitro structure	All food producing species	5 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on 1 July 1993 The combined total residues of all substances within this group should not exceed 5 µg/kg

1.1.4 Nitroimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.4.1 Dimetridazole	All residues with intact nitroimidazole structure	All food producing species	10 µg/kg	Muscle, liver, kidney fat	Provisional MRL expires on 1 January 1994
1.1.4.2 Ronidazole	All residues with intact nitroimidazole structure	All food producing species	2 µg/kg	Muscle, liver kidney, fat	Provisional MRL expires on 1 January 1994

1.1.n Other chemotherapeutics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.1.n.1 Dapsone	Parent drug	All food producing species	25 µg/kg	Muscle, liver kidney, fat	Provisional MRL expires on 1 January 1994
			25 µg/kg	milk	

1.2 Antibiotics

1.2.2 Tetracyclines

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
All substances belonging to the tetracycline group	Parent drug	All food producing species	600 µg/kg	Kidney	Provisional MRLs expires on 1 January 1994. The combined total residues of all substances within the tetracycline group should not exceed the limits indicated
			400 µg/kg	liver	
			200 µg/kg	eggs	
			100 µg/kg	muscle,	
			100 µg/kg	milk	

1.2.3. Macrolides

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.3.1. Spiramycin	Parent drug	Bovine, porcine	300 µg/kg 200 µg/kg 50 µg/kg	Liver kidney muscle	Provisional MRLs expire on 1 July 1995
		bovine	150 µg/kg	milk	The MRLs for liver, kidney and muscle apply to both the bovine and porcine species
1.2.3.2. Tylosin	Tylosin	bovine porcine poultry	100 µg/kg	muscle liver kidney	Provisional MRLs expire on 1.7.1995
		bovine	50 µg/kg	milk	

1.2.4. Chloramphenicol and related compounds

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
1.2.4.1. Chloramphenicol	Parent drug	All food producing species	10 µg/kg	Muscle, liver, kidney, fat	Provisional MRL expires on July 1994

2 *Antiparasitic agents*

2.1 Agents acting against endo-parasites

2.1.1 Benzimidazoles and pro-benzimidazoles

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.1.1. Febantel 2.1.1.2 Fenbendazole 2.1.1.3. Oxfendazole	combined residues of oxfendazole, oxfendazole sulfone and fenbendazole	All food producing species	1 000 µg/kg 10 µg/kg 10 µg/kg	Liver muscle, kidney, fat milk	Provisional MRLs expire on 1 July 1995 The MRLs cover all residues of febantel, fenbendazole and oxfendazole
2.1.1.4. Albendazole	Sum of albendazole and metabolites which are measured as 2-amino-benzimidazole sulphone	bovine ovine	100 µg/kg 500 µg/kg 1 000 µg/kg	muscle fat milk kidney liver	Provisional MRLs expire on 1. 1. 1996.
2.1.1.5. Thiabendazole	Sum of thiabendazole and 5-hydroxythiabendazole	bovine ovine caprine	100 µg/kg	muscle liver kidney fat milk	Provisional MRLs expire on 1. 1. 1996.

2.1.2 Tetra-hydro-imidazoles (imidazolthiazoles)

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.1.2.1 Levamisol	Parent drug	All food producing species	10 µg/kg	Muscle, liver, kidney, fat, milk	Provisional MRL expires on 1 January 1995

2.2 Agents acting against ectoparasites

Pharmacologically active substances	Marker residue	Animal species	MRLs	Target tissues	Other provisions
2.2.1. Amitraz	Sum of amitraz and metabolites which are measured as 2.4-dimethylaniline	porcine	50 µg/kg 200 µg/kg	muscle kidney, liver	Provisional MRLs expire on 1. 7. 1994

3 *Agents acting on the nervous system*

3.1 Agents acting on the central nervous system

3.1.1 Butyrofenone tranquillizers

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
3.1.1 Azaperone	Azaperol	All food producing species	100 µg/kg 50 µg/kg	kidney liver, muscle, fat	Provisional MRLs expire on 1 January 1996

3.2. Agents acting on the autonomic nervous system

3.2.1. Anti-adrenergics

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
3.2.1 Carazolol	Parent drug	All food producing species	10 µg/kg 5 µg/kg	Liver, kidney muscle, fat	Provisional MRLs expire on 1 July 1995

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ANNEX V

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SUMMARY OF THE EVALUATIONS

OF THE SAFETY OF THE RESIDUES OF SUBSTANCES

USED IN VETERINARY MEDICINAL PRODUCTS

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(In accordance with Council Regulation (EEC) 2377/90)

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In order to assist the Commission in establishing legally binding Maximum Residue Limits, the CVMP has evaluated the safety of the residues of the following substances :

Attached are the summary assessments of these substances.

CHLORAMPHENICOL

1. Chloramphenicol is a highly active broad spectrum antibiotic active against the main pathogenic gram negative bacteria of food producing animals. Owing to its excellent capacity for overcoming permeability barriers, chloramphenicol spreads quickly throughout all organs, tissues and body fluids, forming residues in all edible tissues and other animal products intended for human consumption. The use of chloramphenicol in food producing animals is prohibited in some countries, including Denmark and Ireland.

2. The most severe toxic side effect of chloramphenicol, which was described shortly after its introduction in human medicine, consists of a usually irreversible type of bone marrow depression leading to aplastic anaemia. Some evidence suggests that this disease may occur in sensitive human individuals as a result of genetically determined predisposition. The appearance of this adverse effect seems not to be related to frequency, duration or levels of exposure to the drug. Thus a no-effect level cannot be established and an acceptable daily intake cannot be allocated. In these circumstances, residues of chloramphenicol in food must be avoided.

3. The biotransformation of chloramphenicol follows several different pathways. The parent compound is the best suited marker metabolite for monitoring studies in muscle meat, milk and eggs. Recent kinetic studies show that a rapid initial decrease of residue concentrations in tissues and products of food animals is followed by a slow phase of depletion. This makes extended withdrawal periods necessary between the last administration under normal conditions of use and the production of foodstuffs from treated animals.

4. In the case of eggs and milk, the residues which are likely to occur at a zero withdrawal time cannot be considered to be without any potential harm for human health. Moreover, the observance of the necessary extended withdrawal periods in egg and milk production is considered impractical. Therefore, on the basis of the information available, the Committee for Veterinary Medicinal Products recommends that chloramphenicol should not be used in laying birds or lactating animals.

5. On the other hand, the Committee for Veterinary Medicinal Products agreed that chloramphenicol does play an important role in the treatment of other food producing animals, provided that long withdrawal periods can realistically be observed. Where the administration of chloramphenicol to such animals is considered indispensible, its use should be limited to the amounts strictly necessary. Moreover, the observance of the necessary withdrawal periods should be monitored by analytical methods sensitive to residue levels at or below 10 µg/kg.

6. Appropriate analytical methods sensitive to levels of 1 µg/kg in milk and levels at or below 10 µg/kg in meat are available, and have been the subject of collaborative studies within the Community between the national reference laboratories established in accordance with directive 86/469/EEC.

NITROFURANS

1. 2-substituted 5-nitrofurans, particularly furazolidone, are in worldwide use as veterinary medicines for mass medication of swine and poultry for the control of bacterial and protozoal diseases. It is well known that the application of these substances results in the formation of residues in animal-derived products.

2. Toxicological effects which are relevant for the safety evaluation of residues of nitrofurans in foods for human consumption include their potential mutagenicity or carcinogenicity.

3. Many 5-nitrofurans exhibit mutagenic activity in a variety of bacterial and eukaryotic test systems. In bacteria, reduction of the 5-nitro group is essential for the mutagenicity of these substances. The relative mutagenic properties of individual members depend to a large extent on the nature of the substituent at the 2-position of the furan ring. Several nitrofurans have been investigated for their carcinogenic potential in chronic bio-assays. From the results of such studies it was concluded that nitrofurans can produce tumours in experimental animals and must be assumed as potential human carcinogens.

4. However, the data available is insufficient:
   - to come to any final conclusion with respect to the relevance for human health of the effects observed in test systems;
   - to distinguish definitely between individual members of the nitrofuran group;
   - to determine the toxicological significance of the metabolites, including bound residues;
   - to establish residue levels in foods which can be considered with reasonable certainty to be safe for the human consumer.

5. Considering the impact on veterinary therapy of withdrawing the nitrofurans from use in food producing animals, the Committee for Veterinary Medicinal Products concluded:

"The nitrofurans are a therapeutically important group of veterinary medicinal products which cannot easily be replaced at the present time, particularly in the treatment of young animals. On the other hand, they have carcinogenic and mutagenic properties associated with the reduction of the 5-nitro group and the generation of active metabolites.

The available toxicological data do not allow a threshold level to be established without carcinogenic risk, and residues of intact nitro-group containing substances should only be tolerated at the lowest possible level. At the present time, methods of analysis capable of detecting nitroforms at the level of 5 µg/kg are available.

The Committee recommends that the pharmaceutical industry be required to provide a complete review of toxicological data before 1 July 1993. Thereafter, a reassessment of the use of nitrofurans in veterinary medicine and of the available analytical methods should be undertaken."

federal register

Friday
August 23, 1991

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 510 and 558
Nitrofurans; Withdrawal of Approval of New Animal Drug Applications; Final Rule; Final Decision Following a Formal Evidentiary Public Hearing

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

[Docket Nos. 76N-0172 and 76N-0232]

Nitrofurans; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; final decision following a formal evidentiary public hearing.

SUMMARY: The Commissioner of Food and Drugs is issuing his final decision on the proposal to withdraw approval of the new animal drug applications (NADAs) for two nitrofuran animal drugs: furazolidone (NADAs 11-698, 9-078, 12-051, 9-393, 13-805) and nitrofurazone (NADAs 6-395, 8-142, 9-415, 8-689, 10-741). The drugs are labeled and approved for antiprotozoal use for a wide variety of conditions in poultry and swine.

The Commissioner has determined that nitrofurazone and furazolidone are not shown to be safe under the conditions of use for which they were approved under 21 U.S.C. 360b(e)(1)(B).[1] Additionally, the Commissioner finds that furazolidone and its metabolites have by substantial new evidence been shown to induce cancer in man or animals within the meaning of 21 U.S.C. 360b(d)(1)(I). Thus, he is withdrawing approval for the drugs and is revoking the regulations codifying the approval of these applications in 21 CFR 510.515, 558.4, 558.15, and 558.262, and 558.370. Also, he is affirming with modifications the initial decision of the Administrative Law Judge, who made similar findings.

EFFECTIVE DATE: September 23, 1991.

ADDRESSES: The transcript of the hearing, evidence submitted, and all other documents cited in this decision may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert L. Spencer, Division of Regulations Policy (HFC-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3480.

SUPPLEMENTARY INFORMATION: The purpose of this proceeding is to determine whether the Food and Drug Administration (FDA) should withdraw approval of the NADAs for use in food-producing animals. The effect of this decision is that these two drugs may no longer be marketed in the United States, nor may they be exported except as allowed by law.

I. Introduction

The history of this hearing is set forth in the initial decision (I.D.) and in the notice of hearing (49 FR 34965, September 4, 1984). That entire history will not be repeated here. Briefly, this consolidated proceeding involves two animal drugs that have been used in this country since the 1940's, in the case of one of the drugs, and since the 1950's, in the case of the other drug. The two drugs, furazolidone and nitrofurazone, are part of a chemical class referred to as nitrofurans. In the 1960's, evidence first surfaced that furazolidone caused tumors in laboratory animals. As evidence began to mount, FDA issued a notice of opportunity for hearing on March 31, 1971 (36 FR 5927), proposing to withdraw the NADAs for nitrofurazone on the grounds that it was no longer shown to be safe. A similar notice for furazolidone was issued on August 4, 1971 (36 FR 14343).

Since that time, the sponsors of these drugs (Hess and Clark and SmithKline, sponsors) have brought new data before the agency, which has reviewed the data. A full evidentiary hearing has been held to determine whether the NADAs of these two drugs should be withdrawn on the grounds that the drugs are no longer shown to be safe, and, in the case of furazolidone, whether its NADA should be withdrawn under the Delaney anticancer clause as well.

The Administrative Law Judge (ALJ) issued his I.D. on November 12, 1986, finding that the NADAs should be withdrawn. The ALJ found that furazolidone was an animal carcinogen that should be withdrawn under both the Delaney clause (21 U.S.C. 360b(d)(1)(I), as incorporated in 21 U.S.C. 360b(e)(1)(B)) and the general safety clause (21 U.S.C. 360b(e)(1)(B)). He also found that nitrofurazone, including its metabolites, is an animal tumorigen, and, therefore, a suspect carcinogen that should be withdrawn under the general safety clause. The ALJ also found that the sponsors had failed to provide a reliable method of residue detection for either drug and that the residues of neither drug have been shown to be safe. In addition, he determined that the concentrations of residues of furazolidone were not shown to be below the level of carcinogenic or toxicological concern.

Since the issuance of the I.D., the sponsors have filed briefs and exceptions totalling over 350 pages that take exception to virtually every ultimate and supporting conclusion of the ALJ, and that raise several legal and procedural exceptions as well.[2] Following the filing of exceptions, on August 25, 1987, the Center for Veterinary Medicine (Center) moved to reopen the evidentiary record in order to receive National Toxicology Program (NTP) draft reports of bioassays involving nitrofurazone, one of the drugs at issue here, and nitrofurantoin, another nitrofuran but one not directly at issue here.[3] See GF-1700. On September 21, 1987, the two sponsors of the NADAs also filed motions requesting that these materials be admitted in the record, and in addition requesting that the case be remanded to the ALJ for further testimony regarding the issues raised by the NTP reports.

By an order dated November 2, 1987, then Commissioner Frank Young granted the motions by all parties to reopen the record to admit the draft NTP reports. In response to the sponsors' motion to remand the matter for further testimony, Dr. Young permitted a limited remand to the ALJ. Under the terms of the remand, each party was allowed to submit written testimony concerning the NTP reports from one expert witness who had already testified in the proceeding. The remand order also allowed 1 day of cross-examination to be conducted before the ALJ. Finally, the order allowed each party to submit a supplemental brief following the hearing on the NTP reports. Each party filed its expert's supplemental testimony on January 6, 1988. The hearing on remand was held on February 3, 1988, and supplemental briefs were filed on March 8, 1988. Since that time, the record in this hearing has been officially closed.

After fully reviewing the evidence in the administrative record and the exceptions to the I.D. raised by the sponsors, I find that there is clearly enough evidence in the record to justify the ALJ's conclusion that furazolidone and nitrofurazone are no longer shown to be safe.

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[1] Section 360b(e)(1)(B) contains a reference to "subparagraph (H) of paragraph (1) of subsection (d) * * *." Because, in Pub. L. 100-670, Congress redesignated subparagraph (H) as subparagraph (I), the reference should read "subparagraph (I) of paragraph (1) of subsection (d) * * *." For purposes of the final decision, FDA is interpreting the act as if Congress had made this necessary conforming change.

[2] The exceptions filed by the sponsors in this proceeding exceeded in volume those filed in any other hearing before FDA. Many exceptions were frivolous or trivial.

[3] The final version of this report has been published, but it does not differ from the draft as to any conclusions pertinent to this hearing.

I also find overwhelming evidence in the record to support the ALJ's conclusion that the sponsors have failed to provide a reliable means for detecting residues of these drugs and their breakdown products in animal tissue. Such a detection method is necessary to enable FDA to ensure that no dangerous residues enter the human food supply.

On the basis of the administrative record, I find that I am unable to ensure that foods derived from animals treated with these drugs will contain no more than safe levels of residues of furazolidone, nitrofurazone, and their breakdown products (metabolites). Therefore, I am by this notice withdrawing all NADAs for furazolidone and nitrofurazone.

In doing so, pursuant to 21 CFR 12.130(d), I am adopting the LD. as issued with some modifications as stated below. As to exceptions filed by the parties, I am herein addressing only those that I consider significant. I am not required by law or regulation to address *every* exception made—only those raising "significant" issues. *Simpson* v. *Young*, 854 F.2d 1429, 1434 (D.C. Cir., 1988); 21 CFR 12.120(b) and 12.130(c). Where I do not specifically address an exception of Hess and Clark (H&C) or SmithKline (SK), their exceptions are overruled for reasons stated in the Center's Reply to Exceptions.

I am expressly not ruling on any exception filed by the Center because I believe that doing so is not essential to a decision on the issues in this proceeding. As a result, my failure to address a particular exception by the Center should not be construed as either an affirmance or an overruling of that exception.

II. Initial Findings

1. I reaffirm the statement of the allocation and formulation of the burden of proof in the Commissioner's diethylstilbestrol (DES) decision (44 FR 54852), September 21, 1979) and apply that to this proceeding. Under both the Delaney and general safety clauses, approval may be withdrawn if "new evidence," evaluated together with previously existing evidence, shows that the drug is not shown to be safe. "New evidence" includes any evidence not available at the time the application was approved, tests by new methods, and tests by methods not originally considered applicable. There does not appear to be an issue about the "newness" of the evidence upon which the Center relies. The evidence concerning the nitrofurans was not available at the time they were originally approved.

The proponent of withdrawal, the Center, has the burden of making the first showing (i.e., that the drug is no longer shown to be safe). *Hess and Clark, Division of Rhodia, Inc.* v. *Food and Drug Administration*, 495 F.2d 975, 992 (D.C. Cir. 1974).[4] In *Hess and Clark I*, the court found that FDA has "an initial burden of coming forward with some evidence of the relationship between the residue and safety to warrant shifting to the manufacturer the burden of showing safety." Id. at 993. In the Commissioner's DES decision, Commissioner Kennedy adopted the following formulation of the Center's threshold burden:

"' * * [the Center] must provide a reasonable basis from which serious questions about the ultimate safety of DES and the residues that may result from its use may be inferred."

44 FR 54861.

Once the limited threshold burden has been satisfied, of course, the burden passes to the sponsors to demonstrate safety. *Id.*

There does not appear to be a significant difference between the parties on the subject of the burden of proof. In any case, I find that the ALJ applied the correct standard.

2. I find that cost/benefit considerations are irrelevant under both the Delaney clause and the general safety clause. I agree with the Center's view that *American Textiles Manufacturers Institute* v. *Donovan*, 452 U.S. 490 (1981) is ample authority for the proposition that clauses like the Federal Food, Drug, and Cosmetic Act's (the act) general safety clause do not permit, much less invite, cost/benefit analysis.[5] The sponsors do not seriously argue that such an analysis would be applicable where the Delaney clause applies.

3. The sponsors argue that the rodent studies that indicted nitrofurans as carcinogens did not satisfy good laboratory practice (GLP) standards and, thus, cannot satisfy even the Center's limited threshold burden of proof. I disagree. No one argues that these studies were very good studies by today's standards. However, despite their faults, as explained below, the data that they generated constitute substantial evidence of carcinogenicity—evidence which is sufficient to satisfy the Center's threshold burden.

I should note that FDA's GLP regulations were not even proposed until several years after the nitrofuran bioassays were completed. Even more important, by the terms of the preamble to the GLP regulations, "valid data and information in an otherwise unacceptable study which are adverse to the product * * * may serve as the basis for regulatory action. This disparity in treatment merely reflects the fact that a technically bad study can never establish the absence of a safety risk but may establish the presence of a previously unsuspected hazard." (November 19, 1976, 41 FR 51206 and 51212). To the same effect, see FDA's similar statement in the preamble to the final rule (43 FR 59990).

The report of the NTP ad hoc panel on chemical carcinogenesis testing and evaluation (HF–104) cannot be cited to the contrary: "All studies must serve as an adequate basis for regulatory decisions even though they have protocol deficiencies in number of animals per group, number of dose levels, absent clinical observations, etc." HF–104, 12–4. The panel added that "our intent is *not* to imply that previous studies would or should be judged inadequate on the basis of modern criteria [emphasis added]." Id. at 13.

4. I need not and do not address the question of whether hormonally mediated carcinogens are subject to the Delaney clause. This is because the sponsors have not proven that any compound that is the subject of this hearing is a hormonally mediated carcinogen. See, e.g., Denial of Petition for Listing of FD&C Red No. 3 (February 1, 1990, 55 FR 3520, 3537, and 3541). See also *infra*, pp. 37 ff. In addition, as discussed elsewhere [i.e., see pp. 48 ff], I find that none of the compounds that are the subject of this hearing has been shown to be safe within the meaning of the general safety clause. 21 U.S.C. 360b(e)(1)(B).

5. I agree with the Center [main brief at 82, n. 67] that 10^{-6} is an appropriate risk standard by which to judge nitrofurans and their metabolites. The sponsors, while not directly attacking this standard, did suggest that FDA has in the past allowed greater levels of risk, but they have cited no FDA-approved new animal drug for which higher levels of risk from residue were found.

[4] There are two *Hess and Clark* cases: *Hess and Clark, Division of Rhodia, Inc.* v. *Food and Drug Administration*, 495 F.2d 975 (D.C. Cir. 1974) (hereafter *Hess and Clark I*); and *Rhone-Poulenc, Inc., Hess and Clark Division* v. *Food and Drug Administration*, 636 F.2d 750 (D.C. Cir. 1980) (hereafter, *Hess and Clark II*).

[5] In the Commissioner's DES decision, 44 FR at 54863, FDA said: "The law is clear that FDA may not consider socio-economic benefits in the determination of the safety to human beings of a new animal drug, and I am not prepared to conclude that it permits consideration of human health benefits."

III. "New Evidence That Furazolidone Causes Cancer in Man or Animals"

I will proceed now to consider in some detail the adequacy of the Center's "new evidence that furazolidone causes cancer in man or animals."

A. Evidence of Carcinogenicity—The Four Norwich Studies

The Center's new evidence that furazolidone causes cancer consists of four animal bioassays performed under the auspices of Norwich-Eaton, the original furazolidone NADA sponsor. In 1973 and 1974, CF-195a, GF-195b, GF-196, and GF-197 (collectively referred to as "the Norwich studies"). These studies are summarized in the I.D. at pp. 19–23. In addition to the Norwich studies, the Center relies on mutagenicity studies to demonstrate that furazolidone is a mutagen. If furazolidone is demonstrated to be a mutagen, that fact would lend support to the contention that furazolidone is a carcinogen.

The sponsors contend that the Norwich bioassays are not reliable indicators of cancer for a host of reasons. The most important deficiencies cited by the sponsors include the allegation that the maximum tolerated dose (MTD) was exceeded in several of the tests, so that tumors attributed to the carcinogenic effect of furazolidone were, in fact, the result of toxic stress. The sponsors also contend that the incidence of neoplasms in treated test animals was not statistically significant or was within the historical range for spontaneous tumor generation in the test animals. The sponsors further argue that positive indications of carcinogenicity were based on improper groupings of benign and malignant tumors, or of different tumor types. The sponsors also fault the Norwich studies for failing to comply with GLP regulations that were adopted by FDA after these studies were completed. Among the GLP deficiencies cited by the sponsors were illness in the test animals or impurities in the test substance, which should invalidate the results of the Swiss Mouse Study, according to the sponsors.

To the extent that the Norwich studies do indicate that furazolidone causes benign or malignant tumors, the sponsors argue that furazolidone does not act as a "direct" carcinogen. Rather, they contend, the evidence demonstrates that furazolidone causes cancer only in doses high enough to distort hormone levels in the test animals. It is the change in hormone levels, the argument runs, that actually "causes" cancer in the test animals. The sponsors also claim that the Norwich test data demonstrate that, at low enough levels, the ingestion of furazolidone will have no carcinogenic effect. The sponsors also claim that, because humans and rodents have different hormones, it is unlikely that ingestion of furazolidone-treated animals could cause cancer in humans.

Regarding the mutagenicity tests, the sponsors' strongest argument is that furazolidone was only weakly mutagenic or was shown to be mutagenic only under conditions that are unlikely to be duplicated in mammals. Thus, they argue, these mutagenicity studies are not a reliable indicator of furazolidone's carcinogenic potential.

After a thorough review of the evidence and the arguments in the record, I find, for the reasons stated below, that the Norwich bioassays, while imperfect, satisfy the Center's initial burden of adducing new evidence raising questions about the safety and carcinogenicity of furazolidone that are sufficiently serious to require the manufacturers to demonstrate furazolidone's safety.

I also find that the mutagenicity tests, when considered together with the Norwich studies, add further evidence that furazolidone is, at the very least, a suspect carcinogen, and at worst, is a proven animal carcinogen. I also find that the Norwich studies and the mutagenicity tests, considered together, are inconsistent with the sponsors' claims of a hormonal theory of cancer induction.

1. Maximum Tolerated Dose

I agree with the sponsors that the MTD was exceeded in certain dosage groups of two of the studies. Specifically, I find that the MTD was exceeded in the high- and mid-dose groups in the Sprague-Dawley High Dose Study (GF-195b) and in the high-dose group in the Fischer 344 Rat Study (GF-196). HF-310, p. 21; HF-309, p. 9; GF-1617.1, pp. 9–10; GF-1623.1, p. 21a. The MTD may also have been exceeded in the mid-dose group in the Fischer study (GF-196). HF-309, p. 9; HF-310, p. 21; GF-1617.1, pp. 9–10; Transcript ("Tr.") III, pp. 39, 45–6, 50.

However, in the low-dose Sprague-Dawley Study (GF-195a), I find that the MTD was not exceeded in any test group. HF-310, p. 14; GF-1617.1, p. 9. The sponsors do not contend otherwise. As to the Swiss Mouse Study, the fact that there were no early deaths in males is evidence that the MTD was not exceeded in males. G-1617.1, p. 12. The MTD may have been exceeded in females. However, the weight gain noted in treated animals was comparable to that noted in control animals, suggesting that the toxicity was not due to overdosing. G-1617.1, p. 12; GF-1623.1, p. 22. Even if the MTD was exceeded in the mid- and high-dose females, the results would just confirm the effect seen in lower doses. The results in these mid- and high-dose animals, although not demonstrating relevant carcinogenicity, will not have shown safety either. GF-1623.1, pp. 21–2.

Moreover, neither SK nor H&C argues that the MTD was exceeded in the low-dose group of test animals in either the High-Dose Sprague-Dawley Study (GF-195b) or the Fischer Rat Study (GF-196). I agree that the MTD was not exceeded, based on evidence in the record demonstrating that the test animals in the low-dose groups in both the High-Dose Sprague-Dawley Study and the Fischer Rat Study did not suffer a weight decrement exceeding 10 percent and did not exhibit other characteristics usually associated with toxic dosing. GF-1623.1; Bryan, Tr. XII–67–8; GF-1617.1, pp. 9–10.

After reviewing the evidence concerning every group of test animals whose dosage did not exceed the MTD, I find that, in every case, the animals dosed with furazolidone developed neoplasms that exceeded the controls' rate of neoplasms, and that the difference was statistically significant in most cases.

Specifically, I find that mammary tumors in female rats in the Low-Dose Sprague-Dawley Study (GF-195a) exhibited a statistically significant dose response that is indicative of the carcinogenicity of furazolidone. GF-1615.1, p. 11. I also find that, in the Swiss Mouse Study (GF-197), statistically significant dose-response trends were exhibited respecting bronchial adenocarcinomas or adenomas in both sexes and for lymphosarcomas in males. GF-1618.1, p. 8; GF-1615.1, p. 10.

In the Fischer Rat Study, I find that the incidence of mammary tumors exhibited by rats in the low-dose group was statistically significant when compared to the controls. GF-1617.1, p. 10. I also find that the low-dose Fischer rats exhibited not only increases in mammary tumors but also decreased onset time, increased multiplicity and increased malignancy, all of which indicate that furazolidone is a carcinogen at doses below the MTD. GF-1617.1, pp. 9–10; GF-1623.1, pp. 21–2.

In the High-Dose Sprague-Dawley Study (GF-195b), I find that, even in the low-dose group, whose dose did not exceed the MTD, the evidence demonstrates that 41 out of the 50 treated rats developed mammary

tumors, while only 29 out of 50 control rats developed mammary tumors. GF-195b. p. 32; GF-1623.1. p. 22. Where so large a number of low-dose females developed mammary neoplasms in comparison with the controls. I doubt that acute toxic stress, rather than furazolidone, is the cause. The toxic stress argument is also inconsistent with the clear dose-response relationships generated by this study. GF-1623.1, pp. 11-12; GF-1612.1, pp. 6-7, 10; GF-1617.1, pp. 6, 9, 11; HF-309, p. 16; Tr. X. p. 93; Tr. IV, p. 153.

The fact that test animals in the low-dose groups in the Norwich studies developed neoplasms at rates higher than the controls did demonstrate that findings of carcinogenicity in these studies cannot be dismissed as a byproduct of overdosing. In addition, the types of tumors and neoplasms developed by rodents in groups where the MTD was exceeded do not differ in type or locus from those found in groups where the MTD was not exceeded. GF-1617.1, pp. 9-12; GF-1623.1, pp. 21-2. This continuity of tumor type across dosage groups suggests that not all the neoplasms observed in animals whose doses exceeded the MTD can be attributed to acute toxic stress. See GF-1617.1, p. 11. While I would not rely solely on test data from dosage groups where the MTD was exceeded, I find that the similarity of tumor types between dosage groups above and below the MTD provides additional support for the finding that furazolidone itself, rather than any overdosing, caused neoplasms in the test animals that are indicative of carcinogenicity.

2. Statistical and Biological Significance

The sponsors challenge findings in the I.D. that the incidence of neoplasms in treated test animals are statistically and biologically significant. Statistical significance is concerned with the probability that a given test result occurred by chance, rather than because of the effect that the test is designed to study. Biological significance is concerned with whether the animal harboring a lesion will ultimately become diseased as a result of the lesion. GF-1612.1, p. 2.

The ALJ found that statistical analysis of the tumor data from the four Norwich studies was insufficient to evaluate the effects of furazolidone, and that an evaluation of their biological significance was necessary. I.D., p. 42. The ALJ found the Norwich data to provide ample evidence of biological significance. I.D., pp. 42-6. The sponsors challenge findings of biological significance, arguing that mammary tumors occur spontaneously at a high rate in Sprague-Dawley and Fischer 344 rats (HF-309, pp. 5, 22; HF-310, pp. 15, 18, 28; Tr. III, pp. 57-8). The sponsors also assert that important factors that can affect the incidence, multiplicity, and onset time of mammary tumors—such as age, diet, environment, physical stress, hormonal status, and immunologic competence—were not adequately controlled in the Norwich studies. The sponsors further assert that the mammary tumors found in treated test animals were in fact the result of hormonal disruption and generalized physiological stress in aging animals caused by toxic doses of furazolidone that far exceeded the MTD. HF-309, pp. 22-3; HF-310, pp. 3, 18, 22.

For the reasons stated below, I find that the incidence of neoplasms in test groups whose dosage did not exceed the MTD was, for the most part, statistically significant. Since toxic stress cannot explain away these tumors, which were the same types of tumors found in the higher dose groups, I find that the Norwich bioassays provide ample evidence that furazolidone is an animal carcinogen. Moreover, the increased multiplicity of tumors, decreased onset time, and increased malignancy of tumors in all groups of test animals fed furazolidone are additional evidence that the tumor findings generated by these studies are biologically significant—i.e., that the findings are indicative of the actual or potential carcinogenicity of furazolidone. See p. 20, *supra*.

While I agree with the sponsors that age, hormonal status, physical stress and immunologic competence may have some effect on cancer rate, I am concerned that these factors cannot be controlled in either the target animal population that is fed furazolidone or in the human population that eats food products derived from these animals. Therefore, I reject the sponsors' invitation to ignore test findings raising safety questions where these factors were not controlled.

Accordingly, where, as here, four different animal bioassays involving two different species of rat and one species of mouse all demonstrate that treated test animals have an increased rate of neoplasms even at doses below the MTD, I find this to be biologically significant evidence that the test substance is an animal carcinogen. The bioassays are treated individually below.

a. *The Low-Dose Sprague-Dawley Study.*—Regarding the Low-Dose Sprague-Dawley Rat Study (GF-195a), the sponsors assert that the incidence of mammary tumors in treated females was not statistically significant. G-195a, p. 8; GF-1631.1, p. 8; GF-1616.1, p. 11; HF-310, p. 28. However, the sponsors failed to consider time-to-tumor information or to adjust for differential mortality among dose groups. GF-1623.1, pp. 10-11; GF-1612.1, p. 10; GF-195a, p. 6; HF-310, p. 28; HF-309, p. 16; GF-1617.1, p. 9; GF-1615.1, p. 11; CF-1280, p. 17. Proper statistical analyses of tumor data adjust for different mortality among dose groups. See HF-104, pp. 210-14. Also, the sponsors failed to test for dose-response trends, which make more efficient use of the data and are generally more sensitive in detecting effects than are individual comparisons of each dosage group with the control group. GF-1613.1, p. 2; HF-104, pp. 209-10.

In reviewing the results of the Low-Dose Sprague-Dawley Rat Study, I find a statistically significant increase in mammary neoplasms in females with increasing doses of furazolidone, with P=0.006 when using a trend test and incorporating corrections for differential mortality among the dose groups. GF-1615.1, p. 11; CF-1280, p. 17. I find that the statistical analyses conducted by the Center are valid and in accord with analyses conducted by the NTP (HF-104). I also find that the results in the Low-Dose Sprague-Dawley Study are biologically significant. In addition to showing a statistically significant increase in mammary tumors in dosed females, the test results show increased multiplicity of mammary tumors in female rats as the dosage of furazolidone increased. GF-195a, p. 8. When the multiplicity is expressed as a percentage, the rate is monotonic (i.e., goes in one direction only), ascending, dose-related, and significant. GF-1623.1, pp. 11-12; Tr. IV, p. 153.

A witness for the sponsors testified that the NTP rejects multiplicity of mammary neoplasms in rats as an indication of carcinogenic potential. Tr. XV, pp. 72-3; GF-195a, p. 56. I find that, to the contrary, the NTP draft reports on nitrofurazone (GF-1700, p. 11) and nitrofurantoin [GF-1701, p. 7] list "multiplicity in site-specific neoplasia" as one of the several "key factors" to be considered when evaluating bioassay test data for findings of carcinogenicity. The same witness observed that the incidence of rats in the study with single mammary tumors went down as the dosage of furazolidone increased. Tr. XV, pp. 72-3; GF-195a, p. 56. This statement is misleading. The test results in the Low-Dose Sprague-Dawley study demonstrate that the proportion of animals with mammary tumors increased with dose and that the

proportion of animals with multiple mammary tumors increased with dose. GF–195a, pp. 8, 56; Tr. IX–47; IV–150–3. Obviously, all that has happened is that the proportion of animals in the study with the more severe condition—multiple mammary tumors—has increased with dose, decreasing the proportion of animals with the less severe condition of only a single mammary tumor.

In addition, Norwich, the original study sponsor, conceded that two of the three doses in the study significantly increased tumor multiplicity and "caused significantly earlier onset time of mammary neoplasms and caused significantly decreased survival rates when compared to control female rats." CF–195a, pp. 9–10, 60. The sponsors assert that the decrease in mean time-to-palpable-tumor was only marginally significant in the mid- and high-dose females and was not significant in the low-dose group. However, I find that, after adjusting for the differences in tumor onset times between control and treated animals, there was an increased evidence of benign and malignant mammary gland neoplasms in treated females. GF–1623.1, pp. 10–11; GF–1612.1, p. 10. These were biologically significant. GF–1623.1, pp. 11–12; Tr. XII–55–6; HF–104, p. 167. Also, I find that when the decrease in onset time in the mid-dose and high-dose groups is considered in conjunction with the statistically significant increases in mammary tumors and with the dose-related increase in multiplicity, it provides additional evidence of the carcinogenicity of furazolidone. GF–1612.1, p. 6; GF–1617.1, p. 5; GF–1623.1, pp. 11–12; HF–104, pp. 167, 200–14; Tr. IV, p. 153.

I also find that males in the mid-dose and high-dose groups in the Low-Dose Sprague-Dawley Rat Study exhibited an increase in thyroid follicular adenomas that increased with dose level. GF–195a, p. 24. There is no evidence in the record that a statistical analysis was conducted on these data. Notwithstanding the lack of statistical analysis, the dose-related increase in thyroid follicular adenomas in the mid- and high-dose males is still noteworthy. The same tumor was found in dosed males in the High-Dose Sprague-Dawley Study (GF–195b, pp. 28, 30–34; GF–1623.1, p. 11; GF–1612.1, p. 10; Tr. IX–135; Tr. X–41–2 and in the Fischer Rat Study GF–196, pp. 4, 9–11, 26–7, 34–64; GF–1623.1, p. 10; GF–1612.1, p. 11; HF–309, p. 8; HF–310, pp. 21, 23). I find that: (1) the increased incidence of thyroid follicular adenomas in male rats in three different studies; and (2) the findings of mammary adenomas in females in all four studies combine to provide significant evidence that furazolidone is an animal carcinogen.

b. *The High-Dose Sprague-Dawley Rat Study.* The sponsors' main attack on this study is that the dosage levels exceeded the MTD and that the tumors seen in this study were the result of acute toxic stress. However, although the MTD was exceeded in the high- and mid-dose groups, this finding does not explain away the results generated by this study.

First, I note that, in the low-dose group alone, where the dose did not exceed the MTD, 41 out of the 50 treated female rats developed mammary tumors, while only 29 out of 50 female control rats developed such tumors. GF–195b, p. 24. Unfortunately, I can find no evidence in the record that this comparison was analyzed for statistical significance.

However, when a statistical analysis was performed using only the low- and mid-level dose groups in this study, the incidence of mammary tumors was found to be statistically significant after adjusting for differential mortality. GF–1613.1, pp. 3, 4, 6, 9. Because the same types of tumors were observed in the mid-dose group as in the low-dose group, it is clear that not all the tumors in the mid-dose group can be explained away as the result of overdosing. GF–1617.1, pp. 6, 9; GF–1623.1, p. 11; GF–1612.1, p. 10. Therefore, I find that the statistical significance of the incidence of mammary tumors in treated female rats in the low- and mid-dose groups in the High-Dose Sprague-Dawley Study is evidence of the carcinogenic property of furazolidone.

The evidence demonstrates a statistically significant increase in thyroid follicular adenomas in treated male rats, with P=0.0003 when using a trend test and incorporating corrections for differential mortality among the dose groups. GF–195b, pp. 28, 36–64; GF–1615.1, p. 6; Tr. IX, p. 135; Tr. X, pp. 41–2. Because this calculation includes dosage groups that exceeded the MTD, I would not base a finding of furazolidone's carcinogenicity on this fact alone. However, when this fact is considered together with other relevant evidence in the record, I find that it is further evidence of the carcinogenic potential of furazolidone. The fact that treated male rats in all three of the Norwich studies that used rats developed the identical tumor, including rats in the Low-Dose Sprague-Dawley Study, suggests that this finding is not the result of overdosing. GF–195a, p. 24; GF–195b, pp. 28, 36–64; GF–196, pp. 4, 9–11, 26–7, 34–64; GF–1623.1, pp. 10–11.

The High-Dose Sprague-Dawley Study contained much the same evidence of biological significance as did the Fischer Rat Study and the Low-Dose Sprague-Dawley Study. For example, the High-Dose Sprague-Dawley showed a dose-related increase in multiplicity of mammary tumors and a decreased onset time in treated females. GF–195b, pp. 3, 8, 14–15, 26, 32–3, 36–64; GF–1623.1, p. 11, GF–1617.1, p. 9; HF–309, p. 16. I find substantial credible evidence in the record that both of these factors are biologically significant evidence of carcinogenicity. GF–1623.1, pp. 11–12; HF–104, pp. 167, 210–214; CF 1615.1, p. 4; GF–1612.1, pp. 6–7; Tr. IV, p. 153; Tr. X, p. 93.

In addition to this evidence, the data also showed a statistically significant increase in neural astrocytomas in males, both in all dosage groups and in just the two lower dosage groups, when the data were adjusted for differential mortality rates among the groups. GF–195b, pp. 28, 36–64; GF–1623.1, p. 11; GF–1612.1, p. 10; GF–1613.1, pp. 3–4, 6–9; HF–309, p. 16; HF–310, pp. 19–20. While I would not base a judgment of furazolidone's carcinogenic potential on this fact alone, I find that, when weighed with the other evidence in the record, the increased incidence of neural astrocytomas in males is additional evidence pointing to the ultimate finding of carcinogenicity. Tr. IV–121; Tr. X–36–38, 44.

When all of the above evidence is considered, i.e., the dose-related, statistically significant generation of the tumors reported in this study; the large increase in tumors in the low-dose group; the additional factors evidencing biological significance; and the similarity of these findings with similar studies, as a whole, the evidence from this study is inconsistent with the sponsors' assertions that the tumors reported in this study were the result of overdosing.

c. *The Fischer Rat Study.* In the Fischer Rat Study (GF–196), as noted earlier, even if we limit our review to the low-dose group, which received a dose of furazolidone that was below the MTD, a statistically significant increase in mammary neoplasms in treated animals was demonstrated. GF–1617.1, pp. 9–10.

The sponsors complain that benign and malignant tumors should not have been grouped together for the purposes of analysis. While I disagree with the sponsors for reasons that will be detailed in a separate section, I note that, even without combining benign and malignant tumors, mammary adenocarcinomas (malignant tumors)

alone exhibited a statistically significant dose-related increase in the three dosage groups in this study. GF–1615.1, p. 10. I find that the two factors listed above—the statistically significant increase in mammary adenocarcinomas in females in the low-dose group (which were not dosed above the MTD, GF–1617.1, p. 9) and the statistically significant increase in malignant mammary neoplasms in all dosage groups—are biologically significant evidence that furazolidone is an animal carcinogen. GF–1617.1, pp. 6, 9–10.

In addition several other indicators of furazolidone's carcinogenicity were found in the Fischer Rat Study. When all three dosage groups were considered, test animals fed furazolidone exhibited increases in mammary neoplasms with decreased onset time, increased multiplicity, and increased malignancy. GF–1617.1, pp. 9–10; GF–1623.1, pp. 21–2. While the sponsors complain that data from the mid- and high-dose groups should not be considered because the dose exceeded the MTD, I find that the continuity of tumor type as the dosage increased allows us to consider these findings as additional indications that furazolidone is an animal carcinogen.

As noted earlier, I also find it biologically significant that males in this study developed the same type of tumor—adrenal follicular adenomas—as did the male rats in the Low-Dose Sprague-Dawley Study (in which no dosage group exceeded the MTD) and the High-Dose Sprague-Dawley Study. GF–1623.1, pp. 10, 14–15; GF–1617.1, p. 10; GF–1612.1, p. 11; HF–308, p. 8; HF–310, pp. 21, 23; GF–196, pp. 4, 9–11, 20–7, 34–84. Moreover, furazolidone demonstrated a dose response as to these tumors in this study. GF–1615.1, p. 9; GF–1280, p. 11; CF–1613.1, p. 9. I find this to be additional evidence that furazolidone is an animal carcinogen.

d. *The Swiss Mouse Study.* The sponsors argue that the data in the Swiss Mouse Study (GF–197) are not biologically significant because, after the treatment period ended, the mid- and high-dose females and the high-dose males suffered a high mortality rate that is indicative of severe toxic stress. The sponsors argue that, whether this high mortality was due to environmental factors, intercurrent infection, or doses exceeding the MTD, the study is too flawed to provide evidence on the issue of whether furazolidone causes lung cancer.

I disagree. First, statistically significant dose-response trends for bronchial adenocarcinomas and/or adenomas in both sexes and for lymphosarcomas in males were reported. GF–1613.1, p. 8; GF–1615.1, p. 10. If the tumors were produced by environmental factors or from doses exceeding the MTD, I would not expect to find the clear dose-response relationship that this study evidences. In addition, I agree with the Center that the Swiss Mouse Study may actually understate the incidence of tumors expected from a lifetime exposure to furazolidone. GF–1623.1, pp. 23–4; GF–1617.1, pp. 7–8. This understatement may have occurred because test animals should be exposed to the test substance for 24 months in the standard bioassay (HF–104, p. 186). In the Swiss Mouse Study, by contrast, the test animals were dosed for only 13 months (GF–197, p. 5; HF–309, p. 19) but nevertheless produced positive results. Thus, I find that the data are at least as likely to understate the carcinogenic effect of furazolidone as they are to overstate it.

3. Combination of Tumor Type

The sponsors assert that benign tumors should not be considered in assessing the carcinogenicity of furazolidone, and that benign tumors should not be grouped together with malignant tumors for the purpose of statistical analysis. The sponsors also complain that different types of skin tumors were improperly grouped together for the purposes of analysis.

Benign neoplasms are considered to be indicative of cancer because benign and malignant tumors often arise in the same tissue and may represent a spectrum of tumor development and progression. GF–1623.1, pp. 13–14. In the Fischer Study (GF–196) and in the Low-Dose and High-Dose Sprague-Dawley studies (GF–196a and GF–196b, respectively), benign and malignant mammary tumors were grouped together because benign mammary tumors can progress to malignancy, because they arise in common tissue (mammary epithelium), and because of differences in diagnosis from one pathologist to another. GF–1623.1, pp. 13, 15; Tr. III, p. 84. I find that the grouping of benign and malignant mammary tumors was proper in these circumstances.

I also note that, while the sponsors rely on a finding of the International Agency for Research on Cancer that only malignant neoplasms provide evidence of cancer (see HF–104, p. 279), the NTP, an arm of the Department of Health and Human Services that was set up to conduct toxicology studies, does consider the increase in benign tumors and an increase in a combination of benign and malignant tumors, under appropriate conditions, when evaluating carcinogenicity. HF–104, pp. 226–229, 232; CF–1700, p. 11; GF–1701, p. 7.

I find that, based on the common organ and tissue site and the known tendency of mammary neoplasms to progress to cancer, the consideration of benign mammary neoplasms and their combination with malignant mammary tumors for the purpose of analysis were appropriate in the Norwich studies. I also find that there is no credible or sufficient evidence in the record to the effect that any known tumorigen causes only benign tumors. I also find that, because the decision to withdraw the NADAs for furazolidone rests on the general safety clause as well as the Delaney clause, the evidence in the record that furazolidone causes an increased incidence of benign mammary neoplasms in treated test animals which received doses below the MTD is evidence that, when considered in conjunction with evidence of mutagenicity, supports the conclusion that furazolidone is no longer shown to be safe.

I further find that the combination of various types of skin tumors for the purposes of analysis was proper to determine that carcinogenicity or tumorigenicity of furazolidone. Combining skin carcinomas and epitheliomas is acceptable under the NTP guidelines (HF–104, p. 232). These types of tumors gave statistically significant dose-response relationships in Fisher 344 rats. GF–1613.1, p. 8. While I would not base a finding of furazolidone's carcinogenicity or tumorigenicity on skin tumor data alone, I find that it is additional relevant evidence that, when considered with the other evidence in the record, helps demonstrate the carcinogenic and tumorigenic properties of furazolidone.

In summary, I find that the four Norwich studies, taken as a whole, provide enough evidence of furazolidone's carcinogenic potential to meet the Center's burden of demonstrating new evidence raising questions about the safety of furazolidone that are sufficiently serious to require the sponsors to demonstrate furazolidone's safety, which they have not done. In each of the four studies, the tumor types were biologically significant because each of them has the potential to affect adversely the health of the animal in which they were observed. Moreover, feeding furazolidone to rodents significantly increased the incidence of each type of tumor, and, where mammary neoplasms occurred, it increased their multiplicity and decreased the time to tumor when compared to rodents that were not fed furazolidone. CF–1623.1, pp. 11–2.

4. Historical Range of Tumor Development

The sponsors claim that the rates of mammary, skin and thyroid tumors observed in treated animals in the rodent studies were within the range of historical variation in spontaneous incidence for these tumors. HF–310, p. 22; HF–309, pp. 22, 25. However, the evidence of record does not support the sponsors' claim. I find that the incidence of mammary tumors in the control female Fischer rats of 20 percent (10/49) is below the historical range reported in the record of 31 percent to 46 percent. GF–1413.1, p. 1451; HF–257, p. 10. The incidence of mammary tumors in the low-dose group alone is 28/50, or 56 percent. GF–198, p. 28. I therefore find that the incidence of mammary tumors in treated females in the low-dose group alone in the Fischer Rat Study exceeds the historical range, providing additional evidence of furazolidone's carcinogenic properties.

The record also contains several reasons why tumor incidence may vary from study to study. HF–310, p. 22. This is the reason why valid scientific test protocols require that concurrent control animals be compared with a test group of treated subjects. This concept of concurrently controlled studies is basic to scientific investigation, and FDA cannot allow historical data to contradict concurrently controlled studies.

5. Hormonal Induction

The sponsors argue that, to the extent that furazolidone and nitrofurazone cause tumors, they do so through a hormonal mechanism which occurs only at dose levels over a threshold and, therefore, are not subject to the Delaney clause because the threshold is above any likely human consumption levels.

Based on the record, I draw three scientific conclusions that militate strongly against the argument that furazolidone's tumorigenicity is based solely or even primarily on a hormonal mechanism. First, the increase in non-endocrine tumors discussed in GF–1623.1, GF–1013.1, p. 8, and GF–1615.1, p. 10 is important in showing that a genotoxic (i.e., damaging to deoxyribonucleic acid, thus causing mutations or cancer) mechanism is almost certainly responsible.

Second, the positive results of mutagenicity tests on furazolidone contradict the hypothesis that hormonal induction is the sole mechanism by which the substance induces cancer. GF–709; GF–710; GF–829; GF–833; GF–834; GF–349; GF–850; GF–1620.1, p. 9.

Third, the failure to demonstrate increased plasma progesterone levels in orally dosed animals means that the target organs for carcinogenic action were not exposed to increased progesterone levels. GF–1018, table 8; HF–310, pp. 4–11. Thus, the hormone hypothesis is clearly refuted by the sponsors' own data.

Against these facts, the sponsors cite what they believe is evidence to the contrary. I will consider their contentions.

The sponsors contend that the Low-Dose Sprague-Dawley Rat Study (GF–195a) demonstrates that furazolidone, unlike direct acting carcinogens, causes tumors only at dose levels that cause hormonal disruption. HF–309, p. 29. However, as stated above the rats in this study did develop tumors, demonstrating a dose response, including tumors at doses below those that would cause "hormonal disruption." Thus, the sponsors' entire argument about a hormonal mechanism based on this study has a false premise.

The sponsors cite as "compelling evidence" supporting their hormonal theory (H&C exceptions, p. 114) studies showing that ovariectomy has been shown essentially to eliminate the occurrence of mammary tumors in furazolidone-treated rats, while significant numbers of tumors occurred in nonovariectomized rats.

However, ovariectomy of rats also reduces the incidence of mammary tumors induced by known carcinogens such as 3-methylchloranthrene (3MC) and *N*-nitrosomethylurea. GF–1417; GF–1616.1, p. 12. Both of these compounds are known to be potent genotoxic and carcinogenic substances. GF–1616.1, p. 12. Ovariectomy also reduced the control incidence of mammary tumors from 20 percent to 0 percent in female rats. GF–430, p. 13. Therefore, the diminution of tumors after ovariectomy is not evidence of the absence of a genotoxic mechanism.

The sponsors suggest that furazolidone blocks the synthesis of corticosterone, leading to enhanced production of progesterone and other corticosteroids, which in turn results in mammary hyperplasia. HF–310, pp. 3–11. This the sponsors consider to be further evidence of the existence of a hormonal mechanism.

On the contrary, a feeding study of the effect of furazolidone on plasma steroid levels, GF–1018, Table 8, showed that there was no increase in the plasma levels of progesterone at the highest dosage level. Thus, the thesis that increased progesterone levels caused by furazolidone are responsible for mammary tumors gains no support. The sponsors attempt to explain away the fact of decreased plasma progesterone levels at the high furazolidone dose by invoking a complex "adrenal adaption" theory, but their "evidence" acknowledges that "weather [adrenal adaption] could lead to mammary tumor formation remains obscure." GF–1011, p. 8. Hence, the sponsors have adduced no evidence for this theory.

I find that the data support the proposition that furazolidone can act as a direct carcinogen: in intact rats, no plasma progesterone increases were seen (GF–1018, Table 8); no change in progesterone-sensitive organs was seen (GF–195b); and mammary tumors were induced. GF–195b, pp. 32–3.

The sponsors also argue that the patterns of tumorigenesis in the four Norwich studies are "characteristic" of hormonal disruption (SX–187, pp. 6–7; Tr. IX–20A; HF–309, pp. 8–9), but their theory fails to explain the statistically significant increase in nonendocrine tumors found in these studies. See *supra*, pp. 19 and 30 and GF–1613.1, p. 8; GF–1615, p. 10; GF–1623.

Further, the sponsors argue that the hormonal mechanism in the rat is not duplicated in human physiology because the function of corticosterone in the rat is performed by cortisol in humans. Because of this difference, they say, the hormonal derangements caused by blocking the synthesis of corticosterone in the rat is less likely to occur in humans. Tr. X–63, 73. According to the sponsors, the evidence shows the rat to be a poor model for predicting the effects of furazolidone in humans because corticosterone is not the primary messenger regulating human hormonal balance. HF–309, pp. 3–4, 6–8, 15–8; HF–310, pp. 4–11, 27–30.

However, my examination of the evidence has revealed that the hormonal mechanism of tumor induction is not unique to the rats but has a physiological analog in man. Tr. X–61–65; Tr. IV–108–111. Hence, the difference between cortisol and corticosterone does not constitute a reason why furazolidone would not have a similar effect in humans.

To conclude, whether or not hormonal changes may occur as a result of acute treatment with furazolidone, as argued by the sponsors, such a mechanism cannot be invoked as the only tumor-inducing mechanism given the evidence of the presence of (1) nonendocrine tumors (GF–1613.1, p. 8, GF–1615.1, p. 10, GF–1623), (2) mutagenic activity (GF–349; GF–850), and (3) the failure of furazolidone to elevate plasma progesterone in any long-term feeding study. GF–1011, pp. 7–8; GF–1018, p. 18.

In fact, the sponsors have not proven that the tumors in the Norwich studies were induced solely by hormonal imbalance. Hence, I reject the sponsors' argument that furazolidone tumors were hormonally medicated.

B. Residue Detection

Having determined that furazolidone is an animal carcinogen at worst, and a tumorigen and suspected carcinogen at best, I now must determine whether residues of furazolidone would remain in animal food products after furazolidone had been given to the animal under the current labeling instructions and whether those residues raise concerns about safety. This determination is necessary under the DES proviso to the Delaney clause (21 U.S.C. 360b(d)(1)(I)(ii)) and is also necessary under the general safety clause. Section 360b(d)(2)(A) states that, in assessing the safety of a drug, I must consider "the probable consumption of such drug, and of any substance formed in or on food because of the use of such drug * * *."

The sponsors have attempted to demonstrate that, under the method of analysis they have proposed, no residues of furazolidone are found in test animals that are 0.5 ppm or greater. H&C exceptions at 132 ff. The sponsors further assert that only furazolidone, and not its metabolites, is covered by the Delaney clause. The argument is based on FDA's regulatory treatment of other chemicals. SK exceptions at 30–33. According to the sponsors, the phrase, "such drug," as used in the "DES Proviso" to the Delaney clause, 21 U.S.C. 360b(d)(1)(I), refers only to the new animal drug which is the subject of the NADA and which has been shown to induce cancer under the Delaney clause. The sponsors contend that the term, "such drug," does not include the metabolites or degradation products of the drug and charge that the ALJ erred in his interpretation of the Delaney clause by stating, on pages 8, 9, and 13 of the I.D., that the residue includes both the parent drug and its metabolites. SK exceptions at 30 ff. The sponsors further argue that, to the extent the metabolites of furazolidone are in question, the metabolites are incapable of harming consumers of food products that may contain these metabolites. H&C exceptions at 127 ff.

After reviewing the evidence and the relevant portions of the statute, I must disagree with the sponsors on every point. First, I find credible evidence in the record that residues of furazolidone as high as 3.62 ppm were recovered in animals fed furazolidone under conditions of use specified in the label (GF–1618.1, pp. 5, 7; GF–883; GF–894; GF–1078, p. 39; GF–1007, p. 33). These residue levels far exceed the 0.5 ppm level claimed by the sponsors to be of no carcinogenic concern. SX–182, p. 7; HF–307, pp. 5–6; SX–183, p. 15; Tr. X–17–19.

I also find that both the general safety clause and the Delaney clause require the agency to consider the effect that the consumption of drug residues, including metabolites, will have on human consumers. As noted above, the general safety clause, 21 U.S.C. 360b(d)(2)(A), specifically requires the agency to consider this factor when reviewing an original application for an NADA. When the agency considers whether to withdraw an NADA for safety reasons under section 360b(e)(1) of the act, the agency certainly may consider the safety factors mandated by Congress in section 360b(d). See DES Commissioner's Decision, 44 FR 54852. To hold otherwise would be inconsistent with the clear intent of Congress in passing safety legislation intended to protect the American public from ingesting potentially harmful drug residues in food products.

These sponsors' arguments that nitrofurans' metabolites are not of carcinogenic concern are both contrary to principles acknowledged by the parties (Combined Critique of Center for Veterinary Medicine's Allegations of Facts, ¶¶ 208–9) and the law of this proceeding (49 FR 34971 and 34973, September 4, 1984).[5]

More importantly, interpreting the Delaney clause so as not to defeat its purpose requires that FDA find that the clause comprehends metabolites as well as parent drugs. The Center reminds us (Replies to Exceptions, pp. 26–7) that animal drugs may (1) be less carcinogenic than their metabolites, (2) leave no trace of parent compound in the edible tissue of the treated animals, and (3) cause no adverse effects to the treated animals. Hence, the sponsors' interpretation would compel FDA to conclude that dangerous human carcinogens could not be banned under the Delaney Clause. I reject this interpretation.

H&C claims that the court in *Hess and Clark I* accepted its interpretation of the term "residue." However, the language to which H&C refers, 495 F.2d at 991, was, in context, a reference to H&C's argument that the residues were actually attributable to the impurity, "pseudo-DES," not DES residues themselves. Neither is H&C's reliance on *Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984) apt. There, the court found that a food additive containing a carcinogenic impurity is not subject to the Delaney clause if the additive, when tested as a whole, does not cause cancer. Here, furazolidone and its metabolites have been shown to cause cancer.

Alleged examples of FDA actions contrary to this position do not form a basis for a contrary conclusion. The sponsors have cited no published FDA document, much less a binding policy statement, in which FDA concluded that the Delaney clause does not apply to metabolites. Nor have they cited a single chemical regulated in a contrary manner.

For the reasons stated above, I find that the Delaney clause does apply to carcinogenic metabolite residues. Therefore, it becomes clear that the sponsors' proposed method of residue detection fails to meet the standards derived from the statute. The sponsors concede that their chosen method of residue detection—the Winterlin method—does not measure total residues, but only residues of the parent compound. HF–260; SX–183, pp. 4–5; Tr. X–11. The Winterlin method of analysis would still be acceptable if the sponsors had provided data demonstrating that the depletion of the measured entity (the "marker") from the measured animal tissue (the "target tissue") bore a known relationship to the depletion of all drug residues of toxicological or carcinogenic concern (December 31, 1987, 52 FR 49582 and 49583); GF–1610.1, p. 4. However, the sponsors have failed to do so. Hence, they have failed to adduce an acceptable method of residue detection that would permit FDA to determine that furazolidone residues remaining in treated animals would be safe to consumers.

The sponsors claim that the evidence demonstrates that none of the metabolites of furazolidone remaining in treated animals would be harmful to consumers. SX–180, p. 3; SX–181, pp. 3–4; SX–182, p. 4. For example, the sponsors claim that the presence of the 5-nitro group in nitrofuran compounds is essential for any mutagenic or carcinogenic activity resulting from its partial reduction into reactive intermediates. SX–182; SX–181; SX–182; HF–308; SF–36.

However, my review shows that the evidence indicates that metabolites of furazolidone without the 5-nitro group do have some mutagenic activity. Aminofuran and acetamidofuran, for example, tested both with and without

[5] * * * in the absence of information to the contrary, all drug-related residues, including metabolites are presumed to be potential carcinogens, and must be taken into account in determining if there is 'no residue.'" 49 FR 34973.

activation, are mutagenic. HF–97, Table 10. Thus, I find that nitroreduction does not necessarily preclude subsequent toxicity.

The evidence shows that there are a number of different metabolic pathways for the breakdown of furazolidone. GF–1631.3. Depending on the pathway, metabolites that still retain the furan ring with the 5-nitro group may be formed. Further, metabolites having the 5-nitro group were detected in the urine of animals treated with furazolidone. GF–712; GF–751. These metabolites included the "415" metabolite, of which the sponsors provide only unsupported speculation concerning nonmutagenicity, but which does not seem to have been investigated. HF–307, p. 18. Hence, I find that this metabolite has not been proven safe.

I also find that at least two metabolites of furazolidone are mutagenic. The sponsors have cited SF 38 to demonstrate to the contrary. However, after examining SF 38 (pp. 9–10), I find that two of the acknowledged metabolites of furazolidone—specifically, aminofuran and acetamidofuran—are mutagenic. For the reasons stated at p. 57, *infra*, I find that mutagenicity is an indication of carcinogenicity as well as a separate health hazard.

The sponsors contend that all the metabolites in the tissues after the required 5-day withdrawal period are harmless because the free metabolites are water soluble and excreted. Tr. XI–72. They claim that the remaining residues are in the form of adducts, which are covalently bound forms of metabolites that are not reactive, and, therefore, are not of carcinogenic concern. SX–182; pp. 4, 6–7, 10; SX–180, pp. 3, 10; SX–181, pp. 4–5, 7–10; HF–307, pp. 8–10, 12–14. However, my examination of the evidence contradicts this position, indicating that not all of the drug is excreted, and that there are significant amounts of extractable residue of furazolidone present in animal tissue, even 14 days after drug withdrawal. GF–558; GF–1818.1, p. 11; GF–1079, pp. 1, 14. This implies that there are unbound residues in the tissue or that the bound residues are unstable. Protein adducts may pose a toxicological hazard if they are not stable, according to the evidence. GF–1459, pp. 2–3; GF–1545, p. 45. Since the nature of these residues and their toxicity were not evaluated, they cannot be regarded as safe.

The sponsors cite further evidence to show that, even if the potential adducts were consumed in treated tissue by humans, and subsequently hydrolyzed, no threat would be posed to human health or safety. HF–307, p. 10. However, after reviewing the evidence, I find that hydrolysis in the human digestive system can free adducts, including semicarbizide, which has been shown to be carcinogenic. Tr. XI–80, 82–4. Residues of furazolidone are clearly bioavailable. HF–78. Inasmuch as the identity of all of these residues is not known, toxicity and carcinogenicity of these compounds cannot be determined, and they cannot be considered safe. GF–1618.

I also find that not all the metabolites of furazolidone are known, and that their safety, given what we know of the other metabolites of furazolidone, cannot be assumed. HF–310, p. 14; GF–1617.1, pp. 9, 12; GF–1623.1, p. 22. On the basis of the factual evidence in the record, I find that the Winterlin method of analysis is an unacceptable method of residue detection until the sponsors can demonstrate that the marker—the measured substance—bears a known relationship to the depletion of the total drug residue.

Contrary to the sponsors' assertions, the evidence fails to demonstrate that furazolidone's metabolites pose no health risk to the human consumers. Given all the other evidence in the record demonstrating that furazolidone is a carcinogen and that its metabolites are mutagens, I find that, contrary to the sponsors' assertions, the metabolites of furazolidone pose a potential health risk to human consumers. Because the sponsors have failed to adduce a method of detecting furazolidone's total residues that measures, even indirectly, the depletion of these residues from treated animals, I cannot determine that, under the methods of use specified in the labeling, no residues of carcinogenic or toxicological concern remain in the animal or food products derived from them.

Accordingly, I find that the NADAs for furazolidone should be withdrawn under both the Delaney clause and the general safety clause, because I have no reliable method of detecting drug residues that pose a safety threat to human consumers who eat animal products that may contain furazolidone residues. Whereas the act requires me to consider such residues, it is up to the sponsors to show that there is a reliable method to identify and determine the safety of such residues. They have not done so.

C. Mutagenicity

I find that furazolidone is a mutagen. Tr. XII–12–3, 96; SF–36. Mutagenicity is a scientifically recognized indication of potential carcinogenicity. HF 104, p. 22. I agree with Center witness Dr. Rosenkranz that both furazolidone and nitrofurazone "have been documented as mutagenic in systems which are highly predictive of cancer-causing ability." GF–1620.1, p. 013, ¶ 26. Also, the genetic damage brought about by a mutagen is a risk to health by itself, quite apart from its relation to carcinogenicity, as former Commissioner Jere Goyen found in his Cyclamate decision (September 16, 1980, 45 FR 61507). Finally, I find that, insofar as mutagenicity is concerned, the sponsors have demonstrated no safe dose of these two nitrofurans. See Tr. XI–33.

The sponsors claim that, where furazolidone and/or its metabolites are shown to be mutagenic, they are only weakly so and, further, that a weak mutagen is unlikely to be a carcinogen. H&C exceptions at 130; SK exceptions at 98. However, I note that nitrofurantoin, one of the chemicals the sponsors contended was a weak mutagen but not a carcinogen, has since been proven to be an animal carcinogen in a study submitted for the record by both parties. See GF–1701. Therefore, based on the evidence in the record, I find substantial credible evidence that several of the known metabolites of furazolidone are mutagens that must be treated as carcinogens.

III. Nitrofurazone

A. New Evidence That Nitrofurazone Is Not Shown To Be Safe

The ALJ found, on the basis of the evidentiary record before him, that nitrofurazone is an animal tumorigen, and, therefore, is not shown to be safe under the general safety clause. The ALJ further found that no reliable detection method has been demonstrated to detect nitrofurazone-derived residues in edible animal tissue and that the residues of nitrofurazone were not shown to be safe. He concluded that the evidence before him raised serious scientific questions about the safety of nitrofurazone and resulting residues. I.D., p. 75.

Since the issuance of the I.D., the record has been reopened to receive a draft NTP report that finds, on the basis of state-of-the-art bioassays, that there is clear evidence that nitrofurazone is an animal carcinogen. GF–1700. Therefore, this study both strengthens and validates the prior evidence of record, which indicated that nitrofurazone is a suspect carcinogen.

In the face of overwhelming record evidence that nitrofurazone is a

carcinogen and a tumorigen.[7] I find that new evidence demonstrates that nitrofurazone is no longer shown to be safe under the general safety clause. Thus, the Center has carried its threshold burden with respect to nitrofurazone.

D. Residue Detection

The sponsors have offered the same method of residue detection for nitrofurazone that they offered for furazolidone, namely, the Winterlin method. This method is inadequate to detect nitrofurazone-derived residues for the same reason that it is inadequate to detect furazolidone-derived residues. The Winterlin method does not detect residues of any of the metabolites of nitrofurazone, but only of the parent drug itself. HF-260; SX-183, pp. 4-5; Tr. X-11. This omission would not be fatal if the sponsors had demonstrated that the depletion of the parent compound from edible animal tissue bears a known relationship to the depletion of all nitrofurazone residues that are potentially unsafe. However, the sponsors have produced no such evidence. In light of this evidentiary omission, I am unable to determine the probable consumption of the parent drug or "of any substance formed in or on food" (21 U.S.C. 360b(d)(2)) as the result of the use of nitrofurazone in food-producing animals.

I agree with the Center that no concentration of the residue of a drug shown to be a carcinogen, be it in a parent drug or in its metabolites, can be shown to be of no carcinogenic concern. See citations from the Center's main brief at 82-87; Id. at 78. I find that the calculation of an acceptable daily intake (ADI) is inappropriate for a carcinogen. Tr. XV-15-6. Even if such a calculation might be appropriate for a carcinogen, I would have to find that one is not appropriate for these nitrofurans because the ADI approach is based upon observation of a no-observed-effect level, which was not determined in the Low-Dose Sprague-Dawley rat study. See citations found in the Center's main brief at 89.

IV. Other Exceptions

SK excepts to the failure of the ALJ to note that nitrofuraldehyde and 5-nitrofurols retain the 5-nitro group. SK Exceptions at 61. I grant this exception but find that this has no larger implication with respect to other conclusions in the I.D. However, I reject SK's contention that these compounds have low potential for biological activity because of their low mutagenicity and rapid oxidation or reduction and elimination from the animal's body. First, the relationship between mutagenicity and carcinogenicity is qualitative and not quantitative HF-104. Therefore, low mutagenicity does not necessarily indicate negligible carcinogenicity or noncarcinogenicity. As to the rapidity of oxidation or reduction and elimination from the animal's body, I find that there is of record no persuasive evidence that oxidation or reduction rates have any relationship to the toxicological effects of the nitrofurans.

2. I grant SK's exception [Exceptions at 62] to the wording of the I.D. at 51, lines 13-6, concerning whether 4-(pomeanol or 1-aminopyrine are metabolites of furazolidone. The significance of these compounds is that: (1) They are furans without the 5-nitro group, and are thus toxic; and (2) amino-aromatic compounds can be activated to reactive intermediates. Tr. IX-102-3. Granting this exception does not require any further amendment to the I.D.

3. As to evidentiary rulings, I affirm the rulings of the ALJ for the reasons he stated with one exception. I agree with SK that the ALJ erroneously struck portions of the testimony of two witnesses, Doctors Shriner and Olive, on grounds that their testimony was insufficiently supported by citations. Under the Federal Rules of Evidence, all relevant evidence is admissible, except as otherwise provided by law, the Constitution, or the rules of evidence. Federal Rules of Evidence, Rule 402. According to Rule 401, "relevant evidence," means "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." In my view, the testimony of Doctors Shriner and Olive, if believed, would have at least had some tendency to establish SK's contentions in this proceeding. Further, under FDA's procedural regulations (21 CFR 12.94) evidence is not made excludable simply because it contains either no citations or insufficient citations. Therefore, I rule that the ALJ erred in excluding the subject testimony. The Center's objections should have been overruled as objections that went to the weight to be accorded the testimony, not to its admissibility.

Having overruled the ALJ on this admissibility question, I nevertheless find that the testimony of the two witnesses is entitled to very little weight as a result of the deficiencies complained of in the Center's objection. That is, these witnesses' views are entitled to little weight because they were not accompanied by adequate citations to evidence of record or to any other supporting literature. For this reason, although I have considered the testimony of Doctors Shriner and Olive, I give it insufficient weight to cause it to change my mind on any fact in issue in this proceeding. Though error, the exclusion was harmless error.

V. Conclusions and Order

The foregoing opinion in its entirety constitutes my findings of fact and conclusions of law. Based on the foregoing discussion, findings, and conclusions, I affirm the ALJ's initial decision as corrected and supplemented by this decision.

Specifically, I conclude that:

(1) New evidence shows that there is a reasonable basis from which serious scientific questions may be inferred about the safety of furazolidone and nitrofurazone and the residues that result from their use.

(2) Neither nitrofurazone nor furazolidone nor their metabolites have been shown to be safe under the conditions of use upon the basis of which the applications were approved within the meaning of 21 U.S.C. 360b(e)(1)(B).

(3) No reliable detection method has been demonstrated to be able to detect nitrofurazone-related residues in edible tissues when conditions of use approved in the NADAs are followed.

(4) The residues of nitrofurazone and furazolidone have not been shown to be safe.

(5) The Winterlin method of detection is incapable of measuring the metabolites of furazolidone. No other method of detection has been demonstrated to be able to measure these metabolites. Hence, no reliable method of detection has been demonstrated which is fully adequate to detect furazolidone-related residues in edible tissues when conditions of use approved in the NADAs are followed.

(6) A practical method of detection capable of detecting both the parent drug, furazolidone, and its metabolites does not exist. Therefore, it is impossible to quantify and qualify the nature of the residues of furazolidone.

(7) Furazolidone and its metabolites have been shown by substantial new evidence to induce cancer in man or animals as prohibited by 21 U.S.C. 360b(d)(1)(I).

(8) A determination of the concentration of drug residues

[7] There is ample evidence of record that tumorigens (inducers of benign tumors) can also be carcinogens (inducers of malignant tumors). CX-1700, p. 7; Tr. III-77-81; Tr. X-112.

consisting of the parent drug, furazolidone, and its metabolites that is of no carcinogenic concern has not been adequately established.

(2) Under the conditions of use specified in the labeling, the actual concentration of drug residues of furazolidone has not been shown to be at or below the level of no carcinogenic concern.

Therefore, I order that the approval of all NADAs for nitrofurazone and furazolidone listed in this document be hereby withdrawn pursuant to 21 U.S.C. 360b(d)(1)(I) and 360b(e)(1)(B). In addition, I order the removal of 21 CFR 558.262 and 558.370. I also order deletions of all references to furazolidone and nitrofurazone contained in 21 CFR 510.515, 558.4, and 558.15.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 708 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.515 [Amended]

2. Section 510.515 *Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act* is amended by removing paragraphs (a)(4) and (a)(5); by removing paragraphs (b)(11), (b)(15), (b)(17)(ii) and reserving them; and in the table in paragraph (c) by removing the entries for "2.", "9.", and "10.", and redesignating entries 11 through 14 as 8 through 11.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

4. Section 558.4 *Medicated feed applications* is amended in the Category II table in paragraph (d) by removing the entries for "Furazolidone" and "Nitrofurazone."

§ 558.15 [Amended]

5. Section 558.15 *Antibiotic, nitrofuran, and sulfanamide drugs in the feed of animals* is amended in the tables in paragraphs (g)(1) and (g)(2) by removing the entries for "Hess & Clark and SmithKline Animal Health Products."

§ 558.262 [Removed]

6. Section 558.262 *Furazolidone* is removed from subpart B.

§ 558.370 [Removed]

7. Section 558.370 *Nitrofurazone* is removed from subpart B.

Dated: August 16, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 91-20219 Filed 8-22-91; 8:45 am]

BILLING CODE 4160-01-M

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MEMORANDUM OF MEETING

NADA 140-973
Date: August 21, 1991
Place: MPN#2, Rockville, MD
Between: Mr. James C. DeCesare
Predident,
Boehringer Ingelheim Animal Health, Inc.

Richard H. Schultz, D.V.M., Ph.D.
Vice President, Research & Development
Boehringer Ingelheim Animal Health, Inc.

&

Dr. Gerald B. Guest
Director, Center for Veterinary Medicine

Dr. Richard Teske
Deputy Director, Center for Veterinary Medicine

Dr. Robert Furrow
Deputy Director, NADE, CVM, HFV-100

Mr. Ed Ballitch
Director, Division of Compliance
Office of Surveillance & Compliance, CVM, HFV-230

Mr. Phil Frappaolo
Acting Deputy Director for S & C, CVM, HFV-200

Mr. DeCesare indicated that his firm had received information from FDA regarding the recent incidents where it was alleged that clenbuterol was used in show animals. He asked how the firm could assist in gathering further information regarding the drug and its uses. He also requested that we keep the firm informed of further developments regarding its illegal use.

Mr. DeCesare indicated that he and Dr. Schultz were to visit with FSIS this afternoon to discuss analytical methods for detection of the drug in tissues. The firm wishes to assist in the development of screening methods for clenbuterol.

Dr. Schultz indicated that clenbuterol is approved in a number of European countries. Its misuse in food-producing animals has been reported in Europe over the past 2-3 years. It is approved as a therapeutic agent in cattle and sheep. It is also approved for use as a bronchodilator in horses.

Dr. Schultz indicated that representatives from their firm had met with authorities in Europe to discuss illegally manufactured (pirated) material. Boehringer Ingelheim's approved clenbuterol product costs between $3-4 per 1.6ug. The dose needed to produce

and maintain the desired muscle definition in a cow would be very costly. The firm believes that approved products are less likely to be used for this reason.

A few years ago a firm in Massachusetts had advertised sales of clenbuterol tablets. The product was tested and found to contain no clenbuterol; however, nicotinic acid had been detected. The product had been said to have been extracted from bovine brain tissue and was being used by body builders.

Dr. Schultz said their firm is not sure that the pirated material seen in Europe is making its way into the U.S.

Dr. Guest asked if the drug is easy to manufacture? Dr. Schultz said that their chemists tell them that it is easy to manufacture; however, the clandestine product is thought not to be very pure. There is a possibility that such a product may be coming out of chemical plants located in Eastern Europe. Their firm does not view these products to be garage or bathtub varieties.

Dr. Guest asked about the effects of overdosing? There have been some reported deaths in horses in New Jersey. A beta-agonist type drug had been detected; however, Dr. Schultz indicated they do not think it was clenbuterol. A veterinarian from the New Bolton Center had called the firm around this time to inquire about clenbuterol and its side effects. The firm said it would appreciate any information we may have uncovered during the New Jersey episode.

Dr. Schultz thought that GC/Mass Spec was the best kind of analytical methodology for detection of clenbuterol. He is aware that such methods exist in Europe. ELISA based tests also exist for screening for the beta-agonist family. They understand that FSIS wishes to validate their recently developed method. Dr. Reagor at Texas A&M has also been in touch with the firm regarding possible methods for detection of clenbuterol.

Dr. Schultz indicated that Boehringer Ingelheim would not seek a food-animal approval in the U.S. They have not developed a method for detection of clenbuterol in tissue. They are aware that race track officials will take action on less that GC/Mass Spec in some states mainly because the technology is expensive.

Dr. Guest asked if their was any correlation between levels of clenbuterol found in urine vs. levels found in tissue? Does it metabolize within 24 hours as some suggest? The firm representatives had no data to share but indicated they would make an effort to deduce the answers and submit information to us. Dr. Schultz did relate to us that the muscle definition seen in show animals begins to decline within 3-7 days after withdrawal of the drug.

Mr. DeCesare indicated that the firm would like to assist in getting some screening tests in place for detection of the drug in

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the urine of show animals. They will pursue their ideas with FSIS.

Dr. Guest asked if the firm had any knowledge of the source of the supply of the alleged pirated material? The firm representatives did not have any information regarding the source of the material; however, they feel the supply is small. Canadian sales of the approved product are said to be limited although some may be making its way into the U.S. Clenbuterol was recently introduced into Mexico but these sales are not thought to be a factor. Some mention of Australia has come up in discussions the firm has had with customers and veterinarians. The equine veterinarians are aware of the product but view its costs as prohibitive in many cases.

Mr. Frappaolo asked the firm representatives whether they had an idea regarding which Eastern European nations may be marketing a clandestine type product? The firm indicated it would try and ascertain the source(s).

Mr. Ballitch asked what forms of the product are in use? Dr. Schultz indicated that clenbuterol comes in the form of granules, as an injectable and in syrup form. It is used therapeutically in cattle and sheep to delay parturition and for pneumonia. Mr. DeCesare gave Dr. Guest a copy of all approved registrations for the product.

Dr. Schultz indicated that the patent has expired for clenbuterol and other firms can now make it legally. The drug had been used for a number of years, but it was not officially approved until the Netherlands established its approval system in 1987.

Dr. Guest asked if man was a particularly sensitive species when it comes to side effects? Dr. Schultz indicated that the product had been used in Europe for years in humans as a bronchodilator. He thought that the individuals that exhibited toxic symptoms in Spain must have eaten a substantial portion of liver in a fairly short period of time. The firm's toxicology people feel that the side effects exhibited by clenbuterol ingestion are the same that you would see for exposure to other beta-agonists. The drug accumulates in the liver and is excreted in the urine. Any such information in their files will be sent to us.

Dr. Guest asked if their had been any Canadian feedback since its approval there? Dr. Schultz indicated that the granules and the injectable products were approved in 1984. The syrup was approved in 1988. The Canadians had indicated to the firm that they would investigate illegal use based on recent events within the U.S. The Canadians were not aware of any illegal uses of the product. Dr. Guest told the firm representatives that FDA could learn from their experiences and information. We would also call the Canadians to see if they had any information that would extend our knowledge regarding use and distribution of the product.

Dr. Teske indicated that confirmation of urine screening results

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would be important to us. Dr. Schultz thought the FSIS method had promise. It is said to be sensitive down to 1ppb while the LOD may be as low as 0.5ppb. Dr. Guest asked which country was doing the most analytically with regards to detection of clenbuterol. Dr. Schultz thought Germany was the largest contributor of methods. The firm will try and ascertain this and report their findings to us.

Dr. Guest thanked Mr. DeCesare and Dr. Schultz for their visit. We agreed to keep each other informed on future developments.

Philip J. Frappaolo

BRIEFING PAPER FOR TRIPARTITE MEETING 1993

Topic: **Clenbuterol**

Background:
Clenbuterol is a beta adrenergic agonist that has not been approved by FDA for any use in the United States. However, it is approved in Canada, the United Kingdom and many other European and South American countries for use to treat respiratory problems in horses, and as a tocolytic agent in cattle in some countries. Clenbuterol residues are present chiefly in liver and kidney. The drug is eliminated in the urine.

In Spain in 1990, clenbuterol residue in beef liver caused the hospitalization of 135 people. Clinical symptoms included increased heart rate, muscular tremors, headache, dizziness, nausea, fever and chills. These symptoms are of particular concern because the toxicity can appear suddenly following the consumption of clenbuterol residue. While no deaths were reported, there was concern about the potential for serious reactions in sensitive individuals, pregnant women, and people with heart disease.

In 1991, the FDA became aware of alleged domestic use of this drug to increase muscle development and decrease fat deposition in cattle, sheep and swine exhibited at livestock shows across the country. It was alleged that some 4-H youths were instructed to use the drug in animals that were to compete in livestock shows. In March 1991, FDA contacted state Departments of Agriculture to inform them of an upcoming investigation into the distribution, sale and use of this drug. In April 1991, FDA and FSIS jointly urged state, local and academic officials to conduct urine screen tests on animals suspected of clenbuterol treatment and to report any positive findings to regional FSIS offices. FDA distributed a letter describing the potential problem with clenbuterol and announced that they would take regulatory action against persons involved in the distribution or sale of clenbuterol. FSIS announced that it would condemn meat that tested positive for residues of clenbuterol. In support of earlier FDA activities, FSIS retained animals with a positive clenbuterol urine screen. Liver samples from carcasses with clenbuterol positive urine were submitted for analysis to the FSIS Midwestern Lab in St. Louis, MO. All liver specimens were negative for clenbuterol and the carcasses were released.

Current Status:
FDA continues to be concerned about the possible adverse health effects in people who might consume food from animals treated with clenbuterol. Clenbuterol is also allegedly popular in the body building athletic arena for its androgenic effects. FDA is continuing to investigate any illegal importation, distribution, sales or use of clenbuterol. FDA/CVM is currently involved in a bulk drug investigation in Wisconsin involving the alleged sale of clenbuterol to veterinarians in Wisconsin and Minnesota for use in dairy cattle. The product sold was indicated for labored breathing, pneumonia, or for "chronic puffers." It carried a 24 hour milk and 4 day withdrawal time.

FSIS is beginning an exploratory study (start date is tentatively July 1, 1993) to sample and test certain classes of livestock for residues of clenbuterol in meat products intended for human consumption. The project will incorporate a two-tiered plan. The first tier will sample from the general populations of selected slaughter classes. The second tier will sample from show animal populations. Samples will be tested by an HPLC method developed by FSIS. (See attached proposal from FSIS on this project.)

9. Clenbuterol

Clenbuterol is a beta-agonist, which is licensed in the UK to treat respiratory disease in horses and calves on veterinary prescription. There is evidence of its abuse as a "growth promoter" in the EC in the form of a feed additive for cattle. Its effect, when given at doses considerably above the therapeutic dose, is to repartition growth, producing more lean mass and less fat. This increases the value of the carcase, at the reputed price of rendering the meat tough and tasteless. In Spain 135 cases of ill-health were described in people after eating calves' liver. There were symptoms and signs consistent with beta-agonist effects associated with high levels of clenbuterol in the remains of the calves' liver, and clenbuterol was detected in the urine of two affected people (Lancet, 24 Nov 1990).

MAFF surveillance has not revealed the presence of residues of clenbuterol in meat or offal that originated in Great Britain. In Northern Ireland, residues have been found at levels that would be unlikely to cause symptoms. Prosecutions have nevertheless been successful in Northern Ireland under the Medicines Act, 1968.

The UK would like to know if there is any abuse of clenbuterol or other ß-agonists in the USA or Canada; if so under what circumstances does such abuse occur?

BULLETIN
BEEF BUSINESS

NATIONAL CATTLEMEN'S ASSOCIATION Vol. 16, Number 30 May 7, 1993

USDA To Propose Safe-Handling Label

USDA announced last week that it will propose regulations to require safe-handling and cooking labels on all meat and poultry products by Aug. 15, 1993. The USDA announcement says the regulations will "mandate labels regarding the handling and cooking of meat and poultry to minimize the chance that bacterial contamination will reach the consumer." Specifics about the format and information specifically required on the label will be outlined when the proposed rules are published. Agriculture Secretary Mike Espy announced in January USDA's intent to require safe-handling labels on meat and poultry products, immediately following an *E.coli* outbreak in the Northwest. Last week's announcement settled a lawsuit filed by Jeremy Rifkin's Beyond Beef Coalition which sought to force USDA to require a label indicating that meat and poultry products contain pathogens with the potential to cause disease. Although Rifkin's lawsuit was filed after Espy's January announcement, Rifkin is attempting to claim victory on the issue.

New Bills On Endangered Species Act

The process of reauthorizing the Endangered Species Act is taking shape in Congress. At press time, endangered-species legislation was being introduced by Sens. Max Baucus (D-Mont.), John Chafee (R-R.I.) and Rep. Gerry Studds (D-Mass.) It appears that some portions are similar to NCA-supported endangered-species legislation, HR1490, introduced earlier this year by Rep. Billy Tauzin (D-La.), but it appears that the Baucus/Chafee/Studds legislation is not as strong in areas such as private property rights protection and accountability for the Fish and Wildlife Service. Last week's legislation is significant because Baucus is chairman of the Environment and Public Works Committee which has jurisdiction over the Endangered Species Act, and Chafee is the ranking member of that committee. Studds is chairman of the Merchant Marine and Fisheries Committee which has jurisdiction over endangered species in the House.

NCA Is Against BST Labeling

NCA opposes required labeling to indicate that foods have been derived from cows receiving supplemental bovine somatotropin (BST), NCA Director of Research and Education Gary Wilson told a Food and Drug Administration (FDA) panel last week. The joint meeting of the FDA Food and Veterinary Advisory Committees was called to determine whether FDA should require food labels to indicate whether BST was used in production of the food, if FDA approves the use of BST. NCA agrees that technologies used to enhance the health and productivity of farm animals should be safe for the animals and the people who will consume the animal products. All decisions to accept or reject such technology should be based on sound science. Scientific evidence from the nation's top science institutions have determined that milk and meat from cows receiving supplemental BST are exactly the same as milk and meat from cows that have not received supplemental BST, Wilson pointed out. "Ignoring the scientific evidence and requiring a BST label claim will result in a misled public believing that somehow a labeled quart of milk or pound of ground beef is different from the non-labeled products."

Strategic Alliances Program Successful

Fifty-three media, producers and industry representatives learned about Strategic Alliances on a tour April 30-May 2. Strategic Alliances is a demonstration project designed to highlight the value of close coordination among industry segments from conception to retail. Tour participants visited the Excel plant in Fort Morgan, Colo., where they learned about packer needs and expectations regarding product consistency. Plant manager Mike Chabot noted that Excel is willing to pay a premium for consistently uniform animals. Participants also travelled to Decatur County Feedlot in Oberlin, Kan., where Strategic Alliances cattle are on feed. Bill Mies of Texas A&M University, a project director, said that Strategic Alliances cattle have demonstrated uniformity and good performance so far. NCA project coordinator Chuck Lambert noted that this project will help identify ways the industry can improve efficiency and profitability.

Participants in the Strategic Alliances tour include: (left to right) Bill Roser, Dan Green, Fred Wortham, Dave True, Bill Mies, Brad Johnson, Don Fahey, Betty Jo Geiger, Dewey Schaffer, Gary Smith, Skip Lawrence, Craig Huffhines, Julie Mettenburg, Jim Sears, Ray Larson, Steve Cornett, Dave Mehlhaff, Richard Lackaff, Genevieve Lackaff, Tom White, Sherry Doubet, Dave Cameron, Polly Grant, Tom Lane, Elmer Hanson, Walther Koers, Bryan Salvage, Joe Don Eilers, John Stowell, Bill Miller, George Thompson, Warren Weibert, Eddie Nichols and Bill Garrison.

Meetings Support Federal Grazing

Western livestock producers during a series of four town meetings have been explaining firsthand to Interior Secretary Bruce Babbitt the importance of maintaining a predictable and equitable fee for grazing on federal lands. In keeping with the Clinton administration emphasis on summits and town meetings, Babbitt called the regional meetings to gather information about how best to resolve the grazing fee issue. He invited environmentalists, livestock producers and local community representatives to participate. Grazing supporters have outnumbered critics by two-to-one. The meetings, which have been held in Bozeman, Mont.; Reno, Nev.; Grand Junction, Colo.; and Albuquerque, N.M. Organizations affiliated with NCA helped coordinate testimony and media support. National and regional media attention has been focused on the meetings. The media included television networks ABC, CBS and NBC, Cable News Network, The MacNeil/Lehrer Newshour, the *Washington Post* and the *Los Angeles Times*. Media personnel visited several ranches to see firsthand improvements cattle producers make on federal lands. They also saw the patchwork federal/state/private land pattern in the West. On a related note, more grazing fee legislation has been introduced in Congress. Rep. Barbara Vucanovich (R-Nev.) has introduced H.R. 1750, which would put into law the current grazing fee formula, and Sen. Frank Lautenberg (D-N.J.) introduced S.781 to arbitrarily increase grazing fees.

EPA Urged To Change Pesticide Policy

NCA has urged the Environmental Protection Agency (EPA) to change a policy that would prohibit feed grains from having even minute amounts of pesticide residues. NCA wrote comments in support of a National Food Processors Association petition requesting EPA to change its policy established in a court decision known as the *Les vs. Reilly* decision. "It is important to note that pesticide residues in feed-quality grains and by-products used for animal feed does not pose any human or animal health safety concerns, according to the National Feed Contamination Database created by EPA," NCA Chairman of Private Lands and Environmental Management Paul Genho of St. Cloud, Fla., wrote. The *Les vs. Reilly* decision would result in increased livestock feed prices, Genho pointed out. "Fewer pesticide products would be available for use, and likewise, a loss of registered pesticide products may reduce production and increase costs of feed grains. These increases would lead to higher beef production costs, and, subsequently, higher prices for beef at the consumer level."

Study Reveals European Beef Is Tainted

European Community (EC) members who refuse to allow American beef into their countries because of professed concern about health effects of growth promotants might want to look more closely at the situation at home. An article in the March 28 London *Sunday Telegraph* says a major reason for the beef glut burdening Europe (the EC has 1.183 million metric tons of frozen beef in storage) is widespread hormone use that is creating larger and larger carcasses. The article cites an unreleased study conducted by the EC which showed 80 percent of cattle in Belgium, 60 percent in Holland, 30 percent in France and 20-25 percent in Britain are tainted with clenbuterol—a drug approved for medicinal use in horses in the United States but considered dangerous when misused as a growth promotant. The drug poses a human health threat, related to liver contamination, caused by eating contaminated meat. In the last six months, the drug has caused two deaths and 350 hospitalizations in Spain and one death and 850 hospitalizations in France. The EC recently tried to limit the size of carcasses that it would accept for its intervention stocks (surplus purchases) program, but member states rejected the plan without explanation. The article concludes by quoting an anonymous senior EC official who says, "I don't eat beef any more, and I used to eat a steak a day."

Calcium Can Enhance Beef Tenderness

Ever hear someone say, "That steak was so tender, you could cut it with a fork." A new program developed by Mohammad Koohmaraie, animal physiologist at the Roman L. Hruska U.S. Meat Animal Research Center, Clay Center, Neb., could make tender beef an every day occurrence. Instead of aging carcasses or cuts of beef for 7 to 14 days to improve tenderness, Koohmaraie has found a way to speed up the process. By injecting a carcass with calcium chloride, muscle breaks down, thus making meat tender. Research shows that the flavor of the meat is in no way jeopardized by the process and the technology may allow the cattle industry to sell beef as a calcium-fortified product. Koohmaraie also speculates that the process will allow breeders to take advantage of desirable traits in cattle without having to worry about the tenderness of the product.

Study Shows: You Aren't What You Eat

Doctors have been selling the idea that people can significantly lower their cholesterol levels by changing what they eat. However, in a recent study financed by Merck & Co., which makes lovostatin, a cholesterol-lowering drug, research indicates that diet may not be the best way to lower cholesterol. The study, conducted on 111 people with moderately high cholesterol levels (240-300), used drug-diet combinations over a 40 week period. With diet only, people do reduce "bad cholesterol", or LDL, the study found. However, the study also found that this was offset by the lowering of "good cholesterol", or HDL. (Good cholesterol protects people from heart attacks.) The use of a cholesterol-lowering drug showed a reduction in bad cholesterol while slightly increasing good cholesterol.

Ag Employment Up But Not On The Farm

In the most recent report on data collected in 1988-89, the USDA Economic Research Service found that farm and farm-related employment grew by almost 323,000 jobs. Those statistics show, however, that most of the increase was in agricultural wholesale and retail trade industries. Farming and farm-related industries provided 23.2 million jobs in 1989, the most recent year for which data are available. Agricultural wholesale and retail trade accounted for the largest share of employment with 13 million jobs while actual farm employment provided 3.2 million jobs. Firms that process and market agricultural commodities provided another 3.2 million jobs. The importance of agricultural jobs varies by state. For instance, the state of California's 2.5 million farm and farm-related jobs account for only about 16 percent of that state's employment while Iowa's 431,000 agricultural jobs provided over 27 percent of total state employment.

Reporters Don't Know Their Environment

The nation's journalists admit they don't do a good job covering environmental issues, says a recent study conducted by American Opinion Research of Princeton, N.J., for the Foundation for American Communications. Based on 512 interviews conducted with print and broadcast journalists, research showed that 72 percent of the journalists surveyed agreed that in general, they lack the training and background to cover stories on technical environmental issues. The study also revealed that journalists, noting that public opinion is derived from news coverage, believe improvements need to be made. Journalists believe the public needs the best possible information to make thoughtful, informed judgments.

from London Sunday Telegraph

One man's meat is another's poison

Europe's hormone mafia pushes up level of dangerous drugs in cattle

by Boris Johnson
EEC Correspondent

THE great Belgian beast heaves itself to its feet with a rippling of muscles like beavers in a sack, delicates ponderously, presenting the curious double buttocks, the dikpil to Flemish, the culard in French, which make its rump perhaps the juiciest provider of steaks of any bull in the world.

This is the Blanc Bleu breed, unique to Belgium. Looking at the tremendous of flesh on this 126-stone animal, and on about 100 similar blond cows and bulls in the barn, steaming and chomping manie mash, it is easy to believe the latest figures from the EEC commissions.

Surplus beef in Europe is more abundant than ever before; individual cattle are, on average, bigger than ever before; and many of them, especially in Belgium, are illegally pumped up with dangerous drugs.

"Of course there is a little bit of hormone in the mash," says the wife, unthinkingly, as she shows us round this farm outside Brussels, before her husband bashes her up.

If she speaks the truth, this doped bull is part of a phenomenon which has helped to leave 1 103 million tons of frozen beef in EEC intervention storage.

If you are a beef cow in Ireland just now, you probably have a less than even chance of being eaten. At one point last year, 80 per cent of Irish animals were being sold into intervention. Some of them have been there for seven years or longer. Most of these swinging green-frosted carcases will never appear in the supermarkets and restaurants of Europe; some of them would probably cause an outcry if they appeared in Ethiopia.

"The beef reforms have failed," admits a senior British agriculture negotiator, referring to the "historic" farm reforms of last year, prod ured by Ray MacSharry, the former farm commissioner. To be more accurate, unlike the price cuts for cereals, they never took place. Big beef subsidies are crucial for Ireland, and Mr MacSharry is Irish.

The glut, say commission officials, has reached this pitch of absurdity for a very simple reason: the sheer size of the cattle being bought in. Partly it is the switch to beef production since the EEC-wide milk quota cuts of 1984, from Friesians to the heavier charolais types; and partly, says "virtually everyone who follows the beef market, it is the influence of growth promoting drugs.

We are talking here largely about clenbuterol. Technically, it is a beta agonist, not a hormone, but it has the same effect. Somewhere in the commission is a report on "hormone" abuse in the Community, the results of two years of labour by 16 veterinary officials from Directorate-General Six, the EEC's farm department. Unusually, they did not rely on data supplied by member states — they went round farms, took blood samples, and saw for themselves.

According to Jaak Vandemeulebroucke, a Belgian Euro MP for the regionalist Rainbow Group, who has seen the report, their findings are astonishing. In Germany, where the offence is punishable by an immediate five year jail sentence, he believes the incidence of hormone abuse is negligible; and in Denmark it is nil.

But 80 per cent of cattle are allegedly affected in Belgium; 60 per cent in Holland, 30 per cent in France and — or at least, so he alleges — between 20 and 25 per cent in Britain.

The Commission has sat on the secret study for nine months, for fear of further disrupting the beef market; and Mr Vandemeulebroucke has paid for his inquisitiveness. Last October, his house was firebombed by the "hormone mafia", a group of thuggish dealers in clenbuterol and other drugs, and he says death threats have been made. Guido Seurinck, a Belgian government vet, resigned from the anti-hormone squad after his house was shot at and his car was bombed.

According to him, cattle drug abuse is universal in Belgium. It's not so much the farmers who do it, as the professional fattenners, the netwerkers. For the last six weeks before slaughter, smallholders send their cattle to middlemen who ladle the stuff in with the feed and water; at some personal risk — inhaling clenbuterol can cause cardiac seizures. But it is worth it. The netwerkers, says Mr Vandemeulebroucke, make about £40,000 per month.

Next week in Belgium alone there will be 25 court cases concerning the hormone mafia. Some will go to prison, but many will escape with the help of Ludo Martens, a top-dollar lawyer, of Ghent. The hormone mafia procures clenbuterol cheaply from Hungary, Romania, or even Argentina.

There is no difficulty, for possession is perfectly legal. The drug is used for horses' respiratory systems and for easing the pains of calving. As a body builder, however, it is banned, like every other growth hormone in Europe. And because it is banned, and because it is so frighteningly effective at putting flesh on a steer, a clenbuterol cocktail can cost £4,000 per pint. Cattle gain weight at up to 17lbs per day, from 800 to 1,300 pounds on just six weeks, worth an extra £300 per head to the Belgian farmer.

For the hard-pressed EEC cattleman, with beef prices forced down by the vast overhang of surplus, using the drug has become a matter of simple commercial nous. If your neighbour's ox is swelling like a gourd in record time, you had better follow suit if you want to compete.

This winter, the commission has tried to set an upper limit on the size of the animals being bought into intervention storage, first 360 kilos (748 9lbs) and then, last week, 380 kilos (837lbs). So far, the proposals have been rejected without much explanation by the beef-producing member states.

In case you think clenbuterol is harmless, says Mr Vandemeulebroucke, remember that in the last six months it has caused two deaths in Spain and 350 people to be hospitalised; in France one person died and 800 have been hospitalised with liver disorders associated with contaminated meat.

"Which brings us to his allegations that the commission report indicates a 20-25 per cent level of clenbuterol use in the UK. If that is what the experts really found, it will almost certainly be airbrushed out by the time the report is published next month. You have to remember that virtually no one has an interest in publicising this problem: not the beef barons, not the retailers, and, faced with a bill for supporting the beef mountain, certainly not the MAFF or the EEC commission.

"They sound like crazy figures to me," says one EEC spokesman, though he refuses to release the report. What point, he asks, in further undermining public confidence in beef, after the ravages of Mad Cow Disease? The official commission line is that Europe is beating the problem. "I'd say it wasn't more than 10 per cent," says an official. Where? "We-ell — overall."

In Britain, the Meat and Livestock Commission proudly points to the UK's spotless record in official tests for "residues". This is confirmed by Mr Chris Bean, who records results for the Government.

"Under our annual survey scheme we found no evidence of clenbuterol in samples of meat taken from slaughterhouses or at retail outlets," he says, choosing his words carefully. He accepts that all traces of clenbuterol can vanish in 28 days, and that meat, as well as drugs, can arrive freely in Britain in the new Single Market.

Just as athletes are becoming ever more adept at finding new mixes of naturally occurring and artificial hormones, the one masking the other, so the hormone mafia uses chemical trickery to foil the analysts.

There are about 4,000 different possible cocktails of clenbuterol, oestrogen and other drugs. In the last two years, 84 new mixtures have been found in Belgium's labs.

As one senior EEC official says tellingly: "I don't eat beef any more, and I used to eat a steak a day. This stuff is not just clenbuterol — it's very dangerous. Some farmers don't know what they've got: they just chuck it in."

Perhaps he is exaggerating: the Belgian government argues that the "hormone mafia" has achieved such notoriety here because of the very scrupulousness of the vets' inspections, and that a drogged bull is in fact a rarity.

Will fact follow fiction as weary President faces up to the Right?

FOREIGN BODIES

PAMELA HARRIMAN, 73

American ambassador.

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History of Clenbuterol Use In Food-Producing Animals And The Enforcement Response

by

G.A. Mitchell, DVM
Director, Office of Surveillance and Compliance
CVM/FDA

at
Veterinary Medicine Advisory Committee

in
Gaithersburg, Maryland

on
November 10, 1993

I am to address the subject of the use of clenbuterol in food-producing animals.

For purposes of this presentation, the horse is not considered a member of the food-producing animal class. The CVM recognizes however that the horse might become human food in its labeling requirements for veterinary drugs with incomplete residue depletion information, that are approved for use in the equine by contraindicating use in food-producing horses. There are no production purpose clenbuterol approvals in any country and there are no INADs in the US for production uses from this sponsor.

This presentation will address the uses of clenbuterol in food-producing animals such as cattle, veal calves, lambs, and swine. These clenbuterol uses will be considered from a world-wide prospective and clenbuterol sources will be considered from all origins including analogues that produce similar therapeutic or metabolic effects and that present new challenges for the forensic or residue chemists.

Clenbuterol, salbutamol, and cimaterol, for example, belong to a group of beta agonists. These drugs and others have been illegally used as performance enhancers in food-producing animals. In particular, they increase meat, reduce fat, and accelerate growth. These drugs have not been authorized for these uses by any country. For purposes of enforcement in respect to food safety, the following beta agonist drugs are of interest:

Clenbuterol	Pirbuterol
Terbutaline	Tulobuterol
Cimaterol	Mabuterol
Salbutamol	Carbuterol

We want to focus our attention today on clenbuterol.

Let's now address public health concerns to answer the question of how clenbuterol use in food-producing animals relates to public health. Very simply, our concern is that clenbuterol residue in liver has been associated with clinical symptoms of illness in people. This is one of the first reports of clinical symptoms in humans from residue of a veterinary drug.

In 1990, 135 patients in Spain presented similar symptoms of tremors and tachycardia within 30 minutes to 6 hours after consumption of liver, the tissue in which clenbuterol residue will be the highest. The symptoms of headache, dizziness, and malaise lasted up to 40 hours. No deaths or major complications were observed. Forty three (43) families were affected involving people from 1 to 68 years of age. The liver was consumed by all but one of the affected individuals. Clenbuterol at 2 to 4 ppb was found in patients urine within 48 hours of eating liver. Clenbuterol was found in 5 samples of unconsumed liver at levels of between 160 and 291 ppb. The investigators reported that treated cattle were sometimes overdosed causing tremors in the animal and immediate slaughter by the owner. The clenbuterol is believed to be from a bulk source of drug. It is not an approved drug source. This would help explain the localized nature of the food poisoning outbreaks in Spain.

Later in 1990 in France, 8 families in 2 different areas were poisoned. The clinical signs appeared in 1 to 3 hours after eating veal liver and disappeared in 1 to 3 days. One patient in France developed marked cardiac palpitations whereas her son did not develop clinical symptoms despite eating the same meal. The suspect veal liver all came from one slaughterhouse and investigations revealed that clenbuterol was used illegally in veal calves in the

area around the slaughterhouse. Owing to the illegal clenbuterol use, the investigators speculate that animals might be slaughtered shortly after the last clenbuterol feeding. Bulk chemical clenbuterol appears to have been the source. The residues were not traced to an approved drug. There was no report of clinical symptoms from people who ate veal meat rather than liver.

The public health concern is based on the association of clenbuterol residues with illness in people. The oral no observed effect level for clenbuterol in people is 5 micrograms/day and pharmacologically active doses of clenbuterol are between 10 and 120 micrograms per day. Based on the Spanish evaluation people who consumed liver could have received 20 to 30 micrograms in a 100 gram serving.

The next subject is a discussion of the sources of clenbuterol. These can be broken down into 4 types.

1. Reagent - This is a highly purified form of the drug which is made in small quantities for use as an analytical standard and sold for comparatively high prices. This form is unlikely to be used for any purpose other than that for which it is intended. The cost is too high.

2. Pharmaceutical - This form is manufactured to meet drug specifications with use limited by the manufacturer to finished drug products. The source provides the clenbuterol products that have been approved in some countries. These products will be described in more detail later.

3. Fine Chemical - This is a raw drug ingredient from competitors of pharmaceutical houses with legitimate business interests in competing for legal sales.

4. Bulk Chemical - The synthesis of clenbuterol is straightforward organic chemistry, requiring only 4 steps from 4-aminoacetophenone. The 4-aminoacetophenone feed stock is inexpensive and listed in several chemical supply catalogs. The reagents are also readily available. Any enterprising person with an organic chemistry background and proper equipment can synthesize clenbuterol.

Clenbuterol is approved in several formulations in a number of countries.

Ventipulmin - Injection solution - 30 micrograms/ml
Ventipulmin - Granules - 16 micrograms/ml
Ventipulmin - Syrup - 25 micrograms/ml or 72.5 micrograms/ml
Planipart - Injection Solution -

These formulations are approved for use in the following animal classes.

	Countries	Equine	Bovine	Sheep	Swine
Injectable	18	18	7	0	0
Granules	18	18	8	0	0
Syrup	10	10	4	0	0
Planipart	14	1	14	12	3

Let's turn now to a discussion of some of what is known about illegal sources of beta agonists outside the U.S. and then to the situation as it can be described in the U.S.

In 1987 and 1988, Canadian authorities were faced with reports of illegal use of clenbuterol in veal calves in Quebec. Ventipulmin had been approved at that time in Canada for use in horses. Residue testing of urine carried out by Agriculture Canada in 1988-89 showed 8 positive samples out of 566 samples tested. All the positive samples were from animals grown in Quebec. Based on my personal involvement with the incident in Quebec, it is my recollection that the source of clenbuterol was believed to be from Western Europe after Canadian authorities had traced its physical movement through a country in South America. In addition, the owners and senior managers of the large veal feeding operations in Quebec were from Holland. The nutrition feeding practices were promoted as having originated in Holland.

Based on newspapers and periodical publications we now know of 3 firms in Holland whose names have been associated with reports of fines brought against them by the courts for illegal use of beta agonists. These are:

HAK - Pharma -	clenbuterol
DOPHARMA -	clenbuterol
ALPURO -	salbutamol

Individuals and firms were recently convicted of selling and using there drugs in veal calves in Holland. While I find this information to be intriguing because it adds considerably to clearing the picture about illegal clenbuterol use in Quebec in 1988, I think for purposes of this presentation it is important only to note that bulk chemical sources of beta agonists including clenbuterol have

been found in use in food-producing animals in Canada and in Holland at least to the satisfaction of Canadian officials and the Dutch courts. I think it is also safe to speculate based on the ease with which clenbuterol can be manufactured that other sources could become available for illegal use in the future.

The FDA issued an Import Alert to stop clenbuterol at border points on March 20, 1991. In FY-93 (ended September 30, 1993), there have been 30 clenbuterol detentions. These shipments originated from the following countries:

Country	No. Detentions
Australia	1
Brazil	2
Canada	2
China	1
Columbia	4
Denmark	1
Dominion Republic	3
France	1
Germany	13
India	1
United Kingdom	1
TOTAL	**30**

These detentions occurred because of deficiencies in labeling, unapproved new drug, or unapproved new animal drug. While detentions are one avenue of defence we can not solely rely on it to protect public health from dangers associated with clenbuterol use in food-producing animals. Based on findings of about 10 years of U.S. bulk animal drug investigations, 56 convictions, and on-going investigations it can be seen that the border protection systems are only partially effective in preventing entry of these illegal products into the U.S.

The United States is in the company of many advanced nations in working to satisfy the need for added safeguards beyond border security in order to better protect public health. One of the most effective means of protecting public health from the dangers of residues in food is residue monitoring.

Several countries have adopted programs that monitor animals at slaughter for clenbuterol residues. The U.S. government including USDA/FSIS and FDA have assayed tissues to monitor for residue and an enlarged monitoring program for this drug is expected to begin in FSIS early in 1994.

A pharmacokinetic knowledge of the clenbuterol is required before a residue monitoring program can be properly designed. What do we know about pharmacokinetics?

The Central Veterinary Laboratory in the UK has conducted a pharmacokinetic study in calves that had been administered 10 micrograms per kg for 21 days. The authors indicate that the liver is the target tissue where edible tissues are to be monitored. This suggestion is consistent with the epidemiology investigations in Spain and France. Clenbuterol residues were quantifiable 2 weeks after drug withdrawal in one study however in other communications,

the UK authors state that clenbuterol residue can be detected for up to 50 days following withdrawal by using an ELISA screening test with confirmation by GC-MS.

The cross reactions for RIDASCREEN® Clenbuterol (Art. No. 1701), one of the ELISA tests, as reported by the manufacturer is shown below.

Time requirement: Sample preparation (ten samples) approximately 1 hour. Test implementation approximately 16 hours (regardless of the number of samples, including a 15 hours incubation overnight).

Detection limit:	Clenbuterol	20 ppt
	Salbutamol and Terbutalin	200 ppt
Recovery rate:	in urine	90%
Cross-reactions:	Clenbuterol	100%
	Terbutalin	10%
	Cimaterol	5.5%
	Salbutamol	11%
	Mabuterol	71%
	Carbuterol	4.5%
	Isoproterenol	4.0%
	Adrenalin	<0.01%

In summary, the analytical technology is available to monitor the liver of animals at slaughter for residues of clenbuterol and to a variable degree for residues of other beta agonists as well.

I have some information in respect to the clenbuterol residue monitoring of animals at slaughter in Canada, Holland, UK, and the US. Many other countries are likely monitoring for clenbuterol residue as well and I apologize to anyone who is offended by the incompleteness of this list.

Canada started its monitoring in 1988-89. They use an ELISA test to monitor urine and confirm findings with a GC-MS assay capable of detecting 1 ppb.

1988/89	Hog urine	304	all negative
	Veal urine	593	8 positive
	Veal liver	117	all negative
1989/90	Hog urine	49	all negative - suspect sampling
	Veal urine	47	all negative - suspect sampling
1990/91	Veal urine	374	all negative - random sampling
1991/92	Veal urine	464	all negative - random sampling
	Veal liver	47	all negative - random sampling
1992/93	Veal urine	433	all negative - random sampling
	Veal liver	143	2 positive - 3 and 9 ppb

Beta-agonists detectable by the methods used in Canada

Carbuterol	Pirbuterol
Cimaterol	Salbutamol
Clenbuterol	Terbutaline
Mabuterol	Tulobuterol

The clenbuterol positives in 1992/93 were from animals grown in Ontario. Investigations revealed the drug used in causing the residue to be _____.

The UK annually monitors liver for clenbuterol residues from about 1000 animals at slaughter and about 200 randomly collected urine samples. They also assay imported retail liver and have found a few positives in these products. They screen the samples using an ELISA test and confirm using the GC-MS method.

Scientists in Holland are regarded as highly competent in their use of ELISA tests and for confirmation of beta agonists, like clenbuterol, with a mass spec. While the newspaper reports from Holland are short in details in this respect it is an easy assumption that this analytical expertise is related to the successful conviction of the 3 Dutch firms mentioned above.

Since 1988, FDA has received numerous scattered reports of the illegal use of clenbuterol in food-producing animals in the US. This notice is most frequently in the form of intelligence information or sometimes simply the assertion of a personal belief. This information has come to FDA personnel at all levels from District Offices to senior officials in CVM.

Except for one unconfirmed report of clenbuterol use in feedlot lambs all reports have outlined a concern about use of the drug in livestock show animals including 4-H projects for cattle, sheep, and swine.

In 1991, CVM sent letters to all state departments of agriculture outlining this concern and sought their assistance in preventing any such use.

Major livestock shows and State Fairs have added a drug testing option that is available to the show officials, to the entry form that must be signed by each competitor.

Clenbuterol was added to the list of drugs that is not permitted for use under Compliance Policy Guide 7125.06 Extra-Label Use of New Animal Drugs in Food-Producing Animals (ELDU).

Allegations of clenbuterol use in cattle, sheep, and swine, show animals including champion class animals were followed up with application of ELISA urine tests and a few on-farm investigations. A liver sample from a show animal at slaughter was assayed by FSIS because the animal had earlier tested positive to a beta agonist urine test. No clenbuterol residues were detected using an HPLC method with sensitivity below 10 ppb.

FDA supports FSIS in their plan to expand the monitoring of animals for clenbuterol residue. Early in 1994, FSIS expects to begin their monitoring of about 2000 samples from heifers, steers, hogs, sheep, and lambs. In addition they will sample from show animal populations. They plan to utilize a GC-MS assay that is sensitive (LOQ) at 1 ppb. FDA is committed to on-farm follow up investigations of FSIS reports of clenbuterol positive animals as the highest priority.

We suspect illegal use of clenbuterol in the show calf is occurring now from the use of ventapulmin syrup approved for use in horses in Canada and smuggled into the US. Individuals have also advised us that they believe bulk chemical clenbuterol is being used in show animals. We have some confirmation of this by the tracking of clenbuterol found at the US border to South American countries.

Our senior enforcement officials are concerned that the approval of the ventipulmin syrup in the US and wider legal availability will increase the illegal use of clenbuterol in food-producing animals. They also argue that approval will make enforcement and conviction more difficult because the FDA must then show a violation of the ELDU policy which is much harder than to show a smuggling violation.

The European Community Commission has adopted a package of proposals aimed at control of residues in meat. One of the proposals, to be considered at a future meeting of the Council of Ministers, would prohibit the use of beta-agonists for all purposes other than the therapeutic treatment of horses and pets. While the outcome of this proposal is subject to further discussions and is uncertain at this time, we note that the proposed approval of Ventipulmin by the FDA is consistent with the proposal.

In summary, we find a new set of enforcment challenges with each new drug approval. It is a more pronounced problem when a new medicinal ingredient is involved. The evidence is clear in respect to clenbuterol that we must address and stop illegal use in food-producing animals now in the presence or the absence of a formal US approval. We have the regulatory tools, pharmacokinetic, and analytical technology and the corporate will to do it. We will find the issue somewhat less clear cut with an approval in hand but I am confident to predict that clenbuterol use in show animals will be greatly reduced within 2 years with or without a clenbuterol approval.

Boehringer Ingelheim Vetmedica GmbH
Bereich International

Product: Ventipulmin®

Form of presentation: Injection solution

Manufacturer: Thomae, Biberach

Registered in:	Date of registration	Species
Argentina	19.09.1988	horse
Australia	July 1986	horse
Belgium	24.03.1983	horse, bovine
Brazil	08.06.1984	horse
Canada	18.07.1984	horse
Columbia	27.02.1984	horse
Denmark	1987 *	horse
Finland	1988 *	horse
France	14.02.86	horse
Germany	14.11.84	horse, bovine
Great Britain	11.01.1980	horse, bovine
Italy	15.06.84	horse, bovine
Mexico	28.05.90	horse
Netherlands	16.03.90	horse, bovine
New Zealand	29.05.84	horse
Sweden	1989 *	horse
Spain	30.04.1981	horse, bovine
Switzerland	June 1987	horse, bovine

* Special permit

Boehringer Ingelheim Vetmedica GmbH
Bereich International

Product: Ventipulmin®

Form of presentation: Granules

Manufacturer: BI KG, Ingelheim

Registered in:	Date of registration	Species
Argentina	19.09.88	horse
Australia	March 1984	horse
Austria	12.08.87	horse, bovine
Belgium	24.03.83	horse, bovine
Brazil	11.07.84	horse
Canada	30.09.83	horse
Finland	1987 *	horse
France	10.08.81	horse
Germany	15.11.84	horse, bovine
Great Britain	11.01.80	horse, bovine
Italy	04.02.82	horse, bovine
Mexico	28.05.90	horse
Netherlands	15.04.91	horse, bovine
New Zealand	06.05.81	horse
South Africa	1984 *	horse
Spain	30.04.81	horse, bovine
Sweden	14.12.90	horse
Switzerland	October 1982	horse, bovine

* Special permit

Boehringer Ingelheim Vetmedica GmbH
Bereich International

Product: Ventipulmin®

Form of presentation: Syrup

Manufacturer: Thomae, Biberach

Registered in:	Date of registration	Species
Belgium	21.05.1990	horse, bovine
Brazil	08.06.1984	horse
Canada	25.08.1987	horse
France	02.01.1990	horse
Germany	06.11.1985	horse
Great Britain	29.01.1991	horse, bovine
Mexico	28.05.1990	horse, bovine
Netherlands	16.03.1990	horse, bovine
New Zealand	26.03.1987	horse
Switzerland	16.10.1990	horse

Boehringer Ingelheim Vetmedica GmbH
Bereich International

Product: Planipart®

Form of presentation: Injection solution

Manufacturer: Thomae, Biberach

Registered in:	Date of registration	Species
Argentina	24.05.1983	bovine, sheep
Australia	April 1987	bovine, sheep pig
Belgium	24.03.1983	bovine, sheep
Brazil	09.08.1984	bovine, sheep pig
Chile	21.09.1984	horse, bovine, sheep, pig
Columbia	24.03.1983	bovine, sheep
Equador	1987 *	bovine, sheep
France	14.02.1986	bovine, sheep
Germany	23.04.1986	bovine, sheep
Great Britain	03.08.1981	bovine
Netherlands	15.04.1991	bovine
New Zealand	12.6.79 /13.8.91	bovine, sheep
South Africa	1987 *	bovine, sheep
Uruguay	01.02.1982	bovine, sheep

* Special permit

(1)

POM

Ventipulmin®

United Kingdom

Veterinary Bronchodilator

Pharmacology
Ventipulmin is a sympathomimetic amine with a high degree of selectivity for the beta$_2$-receptor sites in the body thus providing intense bronchodilating properties with minimum effect on the cardiovascular system. Ventipulmin has been shown to stimulate muco-ciliary clearance in horses and calves.
Ventipulmin is well absorbed following oral administration. Oral and parenteral dose rates are identical at 0.8 micrograms per kg bodyweight.
Onset of effect is similar following oral or intramuscular administration.

Clinical Experience
The effects of Ventipulmin on pulmonary function and clinical response have been assessed in clinical trials with horses and calves suffering from a variety of respiratory conditions.
A marked decrease in intrathoracic pressure, a decrease in respiratory rate, an initial decrease followed by an increase in arterial oxygen partial pressure and clinical improvements were observed.
In addition, a significant reduction in resistance to airflow and a clinical improvement in the animals' respiratory pattern were seen.
There were no significant side effects as a result of treatment in any of the clinical trials. In those conditions where concurrent infection existed, supplementary treatment with antimicrobial agents was instituted.

Presentation
Injection – A clear colourless aqueous solution containing 30 micrograms clenbuterol hydrochloride per ml.
Granules – A white finely grained free-flowing granulate with a hardly perceptible odour. Each gram of granules contains 16 micrograms of clenbuterol hydrochloride.
Syrup – A clear colourless syrup. Each ml contains 25 micrograms of clenbuterol hydrochloride

Uses
Treatment of respiratory disease in horses and calves where airway obstruction due to bronchospasm and/or accumulation of mucus is a contributing factor and improved mucociliary clearance is desirable.
To be used alone or as adjuvant therapy.

In particular:
1. Acute, sub-acute and chronic infections where the presence of mucus and/or micro-organisms may stimulate bronchospasm or cause airway obstruction and thus increase airway resistance. For example, bronchitis, bronchiolitis and bronchopneumonia alone or associated with equine influenza, calf pneumonia and other viral respiratory diseases.
2. Acute, sub-acute and chronic respiratory allergies.
3. Chronic obstructive pulmonary disease (COPD) in horses.

Dosage and Administration
Dosage: Twice daily administration of 0.8 micrograms of clenbuterol hydrochloride per kg bodyweight.
Treatment in calves should be continued for a maximum of up to 10 days.
This dose corresponds to:
Injection – Twice daily administration of 2.7 ml of the injection per 100 kg bodyweight.
Granules – Twice daily administration of 5 g of the granules per 100 kg bodyweight.
The granules should be added to the feed.
The measuring scoop provided with the 500 g pack contains 10 g when full. A scored line on the scoop indicates a half-measure (5 g). Sachets of 12.5 g are available. Each sachet contains sufficient to treat 250 kg bodyweight and may be particularly useful in the treatment of ponies.
Syrup – Twice daily administration of 4 ml of the syrup per 125 kg bodyweight. (One depression of the pump delivers 4 ml syrup).
The syrup should be added to the feed.

Route of Administration:
Injection – Horses: By slow intravenous injection
– Calves: By intramuscular or slow intravenous injection
Granules – Oral
Syrup – Oral

(2)

Contra-indications, warnings etc.
Ventipulmin antagonises the effects of prostaglandin F_2-alpha and oxytocin and is antagonised by beta-adrenergic blocking agents.
If used during pregnancy, treatment must be discontinued at the expected time of delivery since uterine contractions may be abolished under its influence.

Not for use in horses intended for human consumption.

Calves may be slaughtered for human consumption only after 28 days from the last treatment. When using, do not eat, drink or smoke. After use wash any contaminated skin immediately with soap and clean water. When using the granules, avoid inhaling dust.

Pharmaceutical Precautions
Injection – Protect from light.
Granules – Protect from light.
Syrup – Store below 25°C. Protect from light. It is recommended that the pack be used within 30 days of first opening.

Package Quantities
Injection – 10 x 5 ml snap-top ampoules.
Granules – Screw top polythene bottle containing 500 g granules
20 x 12.5 g sachets
Syrup – Screw top polythene bottle containing 365 ml syrup with 4 ml pump dispenser.

Further Information
In cases accompanied by bacterial infection the administration of antimicrobial agents is recommended.
In clinical use it has been noted that following intravenous administration of Ventipulmin to horses, cases of transient mild muscle tremor and sweating were observed. It is suggested that a 'bolus' effect may have occurred in these cases and caused transient peripheral vasodilation.

This vasodilation is a feature exhibited by all beta-adrenergic drugs to a greater or lesser degree and may be minimised by administering Ventipulmin slowly.

Product Licence Numbers
Ventipulmin Injection – 0015/4012
Ventipulmin Granules – 0015/4011
Ventipulmin Syrup – 0015/4032

FOR ANIMAL TREATMENT ONLY

KEEP OUT OF THE REACH OF CHILDREN

Made in Germany

Boehringer Ingelheim

Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell, Berkshire
RG12 8YS

276701/GB/2
9092

Precaution(s): Store in the dark between 2 and 7°C.

Caution(s): Do not vaccinate birds in production. Rehydrate only the amount of vaccine that can be used in one hour.

Warning(s): Do not vaccinate within 21 days before slaughter.

Presentation: V.A. CHICKVAC® - 10 x 1,000 doses lyophilized vaccine, 10 x 200 mL sterile diluent
V.A.-VAC® -10 x 1,000 doses lyophilized vaccine, 10 x 200 mL sterile diluent
V.A. VAC WING-WEB® - 10 x 500 doses lyophilized vaccine, 10 x 5 mL sterile diluent

Compendium Code No.: 2306295

VENTIPULMIN® ℞

Boehringer — **Bronchodilator**

DIN: 80709845 - Syrup
02000102 - Solution

Active Ingredient(s):

Syrup: A colourless, slightly opalescent, viscous syrup with a barely perceptible odour.

Each mL of syrup contains: 0.025 mg (25 mcg) of 4-amino-alpha-[(tert.-butyl-amino) methyl]-3,5, dichlorobenzylalcohol hydrochloride (clenbuterol hydrochloride).

Injectable Solution: A clear, colourless, aqueous solution.

Each mL of solution contains 30 mcg (0.03 mg) of 4-amino-alpha-(tert.-butyl-amino) methyl-3,5, dichlorobenzylalcohol hydrochloride (clenbuterol hydrochloride), and 5 mg of benzyl alcohol as a preservative.

Indication(s): A bronchodilator for the treatment of respiratory disease in horses. For the treatment of respiratory disease in horses where it is considered that airway obstruction is due to bronchospasm.

Pharmacology: The treatment of respiratory disease in horses constitutes a problem that has not been satisfactorily solved, even though many efficient measures are available today.

Pharmacological treatment finds its particular application at the level of either some exogenous stimulus, e.g., infection or some mechanism of bronchial obstruction, e.g. bronchospasm and/or accumulation of mucus. Bronchial obstruction due to the accumulation of secretions has been acted upon by mucolytic and expectorant drugs while bronchial obstructive caused by bronchospasm is relieved by sympathomimetic amines, anticholinergics, corticosteroids and xanthine derivatives.

The sympathomimetic amines have attracted special interest, their clinical application having originated in the demonstrated existence of cellular adrenergic receptors, which are called alpha, beta and gamma according to their response to stimuli. The beta receptors were further subdivided into beta-1 and beta-2. Stimulation of the beta-2 receptors causes a relaxation of the smooth musculature of the bronchi and uterus, and of the beta-1 receptors of the intestinal tract and an increase in cardiac frequency.

Especially interesting for the treatment of respiratory diseases are the beta-mimetic drugs used as bronchodilators. The phenomenon of bronchial spasm is determined by a defect in metabolism at the cellular level and is seen as an increased sensitivity in the bronchial musculature to some chemical mediators such as histamine, acetylcholine, etc., with the consequent phenomenon of bronchospasm. Beta-2 stimulant sympathomimetics, resolve bronchial spasm and consequently improve pulmonary ventilation. In many disease states, both subacute and chronic, the pathological state and the clinical phenomena can persist even when the etiological agent has ceased in its action. The disease still subsists due to the continued disturbances of the physiological processes.

Clenbuterol, the active ingredient in VENTIPULMIN®, as a sympathomimetic amine and has been the subject of intensive research in both man and domestic animals. Due to its chemical structure, a high degree of selectivity for the beta-2 receptor sites in the body has been achieved providing intense bronchodilating properties with minimal effect on the cardiovascular systems.

Other properties attributed to VENTIPULMIN® include excellent absorption from the gastro-intestinal tract following oral administration so that the oral and parenteral dose rates are identical at 0.8 mcg per kg of body weight.

The duration of effects is long lasting and in the range of 6-8 hours after a single application. Once a plateau line has been reached after three to five days, twice a day administration by the oral route has been found to give a satisfactory level of medication, but, where deemed necessary, treatment may be initiated by intravenous administration of the injectable solution.

Dosage and Administration: Twice a day oral administration of 0.8 mcg of clenbuterol per kg of body weight.

Syrup: This is equivalent to one (1) stroke (4 mL) of the metered dosing pump (provided with each package) for each 125 kg (275 lbs.) of body weight twice a day on the grain portion of the feed.

Duration of action is approximately eight (8) hours after a single dose and 12 hours on repeated twice a day dosing.

Injectable Solution: 1.25 mL (containing 30 mcg (0.03 mg) per mL) per 50 kg of body weight given by slow intravenous injections. Use aseptic technique.

Gastrointestinal(s): VENTIPULMIN® antagonizes the effects of prostaglandin $F_{2\alpha}$ and oxytocin. The action of VENTIPULMIN® is antagonized by beta-adrenergic blocking agents.

Precaution(s): Protect from light.

Caution(s): If used during pregnancy, VENTIPULMIN® must be discontinued of the expected time of delivery, since uterine contractions may be abolished under its influence.

Warning(s): Horses treated with this drug must not be slaughtered for use in food.

Side Effects: Infrequently, transient sweating, muscle tremors and mild tachycardia have been observed following intravenous administration. In each instance, the symptoms abated without complications or additional treatment.

Trial Data: (Clinical Experience): In clinical trials, the effects of VENTIPULMIN® on pulmonary function and clinical response were assessed in horses suffering from a variety of respiratory conditions including chronic obstructive pulmonary disease (COPD).

The horses responded by a marked decrease in intrathoracic pressure, a decrease in respiratory rate, an initial decrease followed by an increase in arterial oxygen partial pressure and clinical improvement. Duration of action of a single application was six to eight hours.

Other results showed a significant reduction in resistance to airflow and clinical improvement of the animal's respiratory pattern.

There were no significant side effects due to the treatment in any of the clinical trials. In those conditions where concurrent infection existed, supplementary treatment with chemotherapeutic agents was instituted.

Three separate palatability studies indicated patient acceptance of treated feed. Some animals (55 of 123) exhibited delayed acceptance of treated grain, but done of the horses refused to eat it.

Presentation: Syrup - 255 mL;
Injectable Solution - 50 mL vial.

Compendium Code No.: 3210310

VERAMIX® SPONGES

Upjohn — **Intra-Uterine Progesterone**

DIN: 00613563

Active Ingredient(s): VERAMIX® Sponges are polyurethane sponges impregnated with the progestogen, medroxyprogesterone acetate (MAP). These sponges are for intravaginal use only and are designed to be used with the VERAMIX® sponge applicator.

Each sponge contains:

Medroxyprogesterone acetate	60 mg

Indications: VERAMIX® Sponges are indicated for intravaginal use only for the synchronization of estrus in sheep during the breeding season. VERAMIX® Sponges can also be used to induce cyclical activity in ewes prior to the normal breeding season when sponge use is combined with pregnant mares' serum gonadotrophin (PMSG).

Use During Normal Breeding Season: VERAMIX® Sponges may be used during the normal breeding season.

1. To select in advance the most convenient time for lambing and to plan labour requirements, and
2. To shorten the duration of lambing for the flock to allow intensive care at lambing, improve lamb survival and to make the best use of labour at lambing time.

VERAMIX® Sponges are intended to be used to control the timing of estrus which allows the timing and duration of lambing to be planned. The optimum number of ewes that can be synchronized at one time is determined by the number of fertile rams available at breeding time and the number of lambings that can be handled during the compressed lambing period.

Use to Advance the Breeding Season: VERAMIX® Sponges, in conjunction with pregnant mares' serum gonadotrophin (PMSG) may be used prior to the normal breeding season to induce estrus in ewes at a time when they would otherwise be anestrus. Breeding at this induced early estrus advances the time of lambing and produces lambs for the profitable early lamb market. A carefully controlled production system is required if lambs are to reach marketable condition at the right time. The breed of ewes chosen for early lamb production should be a breed that has a relatively early breeding season naturally, e.g. Dorset Horn, Finn-Dorset, Suffolk or Suffolk half-breeds. Also a fast-growing breed of ram should be used to ensure maximum growth rate; the Suffolk has usually been chosen for this reason.

Dosage and Administration: The use of VERAMIX® Sponges during the normal sheep breeding season involves selecting those ewes that are to be synchronized and ensuring that they are cycling prior to treatment. A sponge is inserted into each ewe for 14 days then removed. Thirty-six to forty-eight hours later, treated ewes will come into heat and should be bred. Those ewes that do not conceive at this first synchronized breeding will cycle normally, showing heat again approximately two (2) weeks later. They can be bred again at this second synchronized estrus.

VERAMIX® Sponges can be used outside of the normal sheep breeding season, if they are used in healthy, well-nourished ewes in conjunction with PMSG. Sponges are inserted for 14 days then withdrawn and PMSG is injected. This combination of sponges plus PMSG will induce estrus in most of the treated ewes and they can be bred 36-48 hours after sponge removal. Generally ewes should not be treated more than six (6) weeks prior to the beginning of their normal fertile season. The earlier the treatment is administered, the fewer will be the number of ewes successfully bred. Ewes that do not conceive to the first mating, usually cycle and can be bred again about two (2) weeks later.

Routine for Administration of VERAMIX® Sponges:

Day 0: All ewes to be synchronized are treated with a VERAMIX® Sponge on the same day. A bucket of clean water containing disinfectant suitable for livestock equipment cleaning should be available to clean the applicator after each use.

1. Each ewe is restrained in a standing position by one (1) operator who will apply the sponges. A second operator applies a thin coating of an antiseptic cream on a sponge and loads it into the VERAMIX® Sponge applicator.
2. The applicator is inserted into the vagina, in a slightly upward direction at first and gently put firmly, pushed forward until it meets resistance.
3. The tube of the applicator is then slipped back out of the vagina, while the rod prevents the sponge from being drawn out. Then the rod is removed leaving the strings protruding from the vulva.

Day 14: The sponges are removed 14 days after insertion. This can vary from 12 to 16 days, but no longer, or conception rates may be adversely affected.

Remove the sponge by pulling on the attached strings with a gentle, steady motion.

If the strings are not visible, insert a clean finger into the vagina to locate them. If the strings or sponge cannot be felt, the ewe may have lost the sponge during the treatment period. A veterinarian should be called to verify that the vagina is empty. Such animals will usually not be synchronized with the rest of the flock.

Sponge loss during the treatment period is more common in maiden ewes and usually the result of the improper placement of the sponges. To prevent such losses, the sponges must be inserted through the hymen and well into the vagina. This may entail rupturing or stretching the hymen in maiden ewes to facilitate the proper insertion of the sponge. Some cases of sponge loss have been attributed to excessive lubrication of sponges and/or applicators with antiseptic creams. To minimize such losses, ensure the antiseptic cream is sparingly applied to sponges only. Normally sponge loss varies from one (1) to four (5) percent.

When pulling on the strings, if the sponge does not come easily, it may be attached to the vaginal wall. Use a clean finger to gently separate the sponge from the wall, then carefully pull the sponge out. Occasionally, the strings may tear through the sponge material when they are pulled leaving the sponge in the vagina. If the sponge cannot be easily located and withdrawn using a clean hand, do not thrust into the vaginal wall in searching for the sponge. A veterinarian should be called to remove the sponge with the use of a speculum and a light.

Day 16-17: Ewes will begin to show signs of estrus about 36 hours after sponge removal but it is usually best to wait until 46 hours after the sponges are removed before introducing

Bert
NOC issued Apr 28/88
for granules
Bill Shannon

Ventipulmin®

Introduction
The treatment of respiratory disease in horses constitutes a problem that has not been satisfactorily solved, even though many efficient therapeutic measures are available today.

Pharmacological treatment finds its parasenta application at the level of either acute congestive episodes, e.g. infection or some reactivement of bronchial obstruction e.g. bronchospasm and/or accumulation of mucus. Bronchial obstruction due to the accumulation of secretions has been acted upon by mucolytic and expectorant drugs while bronchial obstructions caused by bronchospasm is relieved by sympathomimetic agonists, anticholinergics, corticosteroids and xanthine derivatives.

The sympathomimetic amines have attracted special interest, their clinical application having originated in the demonstrated existence of cellular adrenergic receptors which are called alpha, beta and granted according to their response to stimuli. The beta receptors were further subdivided into beta-1 and beta-2. Stimulation of beta-2 receptors causes a relaxation of the smooth musculature of the bronchi and uterus, and of the beta-1 receptors of the intestinal tract and an increase in cardiac inotropism.

Especially interesting for the treatment of respiratory diseases are the beta-mimetic drugs used as bronchodilators. The phenomenon of bronchial spasm is determined by a defect in metabolism at the cellular level and is seen as an increased sensitivity in the bronchial musculature to some chemical mediators such as β-adrenergic acetylcholine, etc., with the consequent phenomenon of bronchoconstriction. Beta-2 stimulant sympathomimetics, reactive bronchial spasm and consequently improve pulmonary ventilation. In many disease states, both subacute and chronic, the pathological state and the clinical phenomena can persist even when the aetiological agent has ceased in its action the disease state results due to the destroyed protective barriers of the physiological processes.

Pharmacology
Clenbuterol, the active ingredient in Ventipulmin, is a sympathomimetic amine and has been the subject of intensive research in both man and domestic animals. Due to its chemical structure, a high degree of selectivity for the beta-2 receptor sites in the body has been achieved providing intense bronchodilating properties with minimum effect on the cardiovascular system.

Other properties attributed to Ventipulmin include excellent absorption from the gastro-enteral tract following oral administration so that the oral and parenteral dose rates are identical as 0.8 mcg per kg body weight.

The duration of effect is long-lasting and in the range of 6-8 hours after a single application. Once a plateau level has been reached after 3-5 days, twice daily administration by the oral route has been found to give a satisfactory level of medication.

Clinical Experiences
In clinical trials the effects of Ventipulmin on pulmonary function and clinical response were assessed in horses suffering from a variety of respiratory conditions including chronic obstructive pulmonary disease (COPD).

The horses responded by a marked decrease in intrathoracic pressure, a decrease in respiratory rate, an initial decrease followed by an increase in arterial oxygen partial pressure and clinical improvements. Duration of action of a single application was 6-8 hours.

Other results showed a significant reduction in resistance to airflow and clinical improvement of the animal's respiratory pattern.

There were no significant side effects due to the treatment in any of the clinical trials in those conditions where concurrent infection existed supplementary treatment with chemo-therapeutic agents was instituted.

Bronchodilator for the Treatment of Respiratory Disease in Horses

Description: Granules. A white freely grained free-flowing granulate with a hardly perceptible odour. Each gram of granules contains 0.016 mg (16 mcg) of amines a - [(tert-butyl-amino) methyl]-3,5-dichlorobenzylalcohol hydrochloride (clenbuterol hydrochloride).

Uses: Treatment of respiratory disease in horses where it is considered that airway obstruction is due to bronchospasm.

Dosage and Administration
Twice daily administration of 0.8 mcg of clenbuterol per kg body weight. This is equivalent to one level measure (10 g) per 200 kg (430 lbs) b.w. added to the feed twice daily. (measure enclosed)

Route of Administration
(1) Granules, Oral

Duration of Action
Approximately 8 hours after a single dose. 12 hours on repeated twice daily dosing.

Contra -Indications
Due to a risk of potentiation of the peripheral vasodilating effects of corticosteroids it is not recommended that these preparations are used in conjunction with Ventipulmin.

Ventipulmin antagonizes the effects of prostaglandin $F_{2\alpha}$ and oxytocin.

The action of Ventipulmin is antagonised by β adrenergic blocking agents.

Caution: If used during pregnancy, Ventipulmin must be discontinued at the expected time of delivery, since uterine contractions may be abolished under its influence. The effect on fertility of breeding stallions has not been determined.

Warning:
Horses treated with this drug must not be slaughtered for use in food.

Protect from light.

Boehringer Ingelheim (Canada) Ltd
Animal Health Division
Burlington Ontario

*Registered Trademark

Printed in Canada 95112A

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500 g

®VENTIPULMIN®

D.N. 566838

Clenbuterol Hydrochloride
Oral Granules ..... 0.016 mg/g
Chlorhydrate de Clenbuterol
granules oraux ..... 0.016 mg/g

Bronchodilator
Bronchodilatateur

Veterinary Use Only
Usage Vétérinaire Seulement

Boehringer Ingelheim

Boehringer Ingelheim (Canada) Ltée
Burlington, Ontario
Canada

84-672-A

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Finland	Tranquilizers	Azaperon	Porcine	100	112	0
France	Antibiotics		Avian	65	93	1
France	Antibiotics		Bovine	5075	870	0
France	Antibiotics		Equine	50	23	0
France	Antibiotics		Ovine	1000	282	7
France	Antibiotics		Porcine	4520	1754	11
France	Chloramphenicol	Chloramphenicol	Avian	65	25	0
France	Chloramphenicol	Chloramphenicol	Bovine	600	417	13
France	Chloramphenicol	Chloramphenicol	Ovine	300	184	4
France	Chloramphenicol	Chloramphenicol	Porcine	300	207	1
France	Heavy Metals	Lead, Cadmium, Mercury	Avian	195	34	0
France	Heavy Metals	Arsenic	Avian	65	34	0
France	Heavy Metals	Lead, Cadmium	Bovine	460	120	8
France	Heavy Metals	Lead, Cadmium	Ovine	200	0	0

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Netherlands	Other Estrogenic Substances	Zeranol, Epizeranol, Zearalanol, Ethinylestradiol	Bovine	3210	3642	0
Netherlands	Other Estrogenic Substances	Zeranol, Epizeranol, Zearalanol, Ethinylestradiol	Caprine	300	16	0
Netherlands	Other Estrogenic Substances	Zeranol, Epizeranol, Zearalanol, Ethinylestradiol	Ovine	300	39	0
Netherlands	Other Estrogenic Substances	Zeranol, Epzeranol, Zearalanol, Ethinylestradiol	Porcine	300	266	0
Netherlands	Other Veterinary Medicines	Clenbuterol	Bovine	1100	1400	15
Netherlands	Other Veterinary Medicines	Clenbuterol	Porcine	100	100	0
Netherlands	Stilbenes	Diethylstilbestrol, Hexestrol, Dienestrol	Bovine	3210	3642	0
Netherlands	Stilbenes	Diethylstilbestrol, Hexestrol, Dienestrol	Caprine	200	16	0

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Hungary	Antibacterials	Antibiotics, Coccidiostatics, Etc.	Ovine	200	0	0
Hungary	Antibacterials	Antibiotics, Coccidiostatics, Etc.	Porcine	6396	15020	18
Hungary	Chloramphenicol	Chloramphenicol	Avian	110	0	0
Hungary	Chloramphenicol	Chloramphenicol	Bovine	132	97	0
Hungary	Chloramphenicol	Chloramphenicol	Ovine	18	0	0
Hungary	Chloramphenicol	Chloramphenicol	Porcine	390	897	18
Hungary	Chlorinated Hydrocarbons	Aldrin, Dieldrin, DDT, DDE, DDD, Alpha-Beta-Delta, Lindane, Heptachlor, Toxaphen, HCB, PCB	Avian	6000	0	0
Hungary	Chlorinated Hydrocarbons	Aldrin, Dieldrin, DDT, DDE, DDD, Alpha-Beta-Delta, Lindane, Heptachlor, Toxaphen, HCB, PCB	Bovine	4060	353	0
Hungary	Chlorinated Hydrocarbons	Aldrin, Dieldrin, DDT, DDE, DDD, Alpha-Beta-Delta, Lindane, Heptachlor, Toxaphen, HCB, PCB	Ovine	1360	0	0

1992 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Japan	Phenoxyls	2, 4 D	Bovine	6	6	0
Japan	Pyrethrins	Permethrin	Bovine	6	6	0
Japan	Sulfonamides	Sulfamonomethoxine, Sulfadimethoxine	Bovine	12	12	0
Japan	Thiamphenicol	Thiamphenicol	Bovine	6	12	0
Japan	Thiocarbonate	Thiobencarb	Bovine	6	6	0
Mexico	Antibiotics	Streptomycin	Bovine	900	145	0
Mexico	Antibiotics	Sulfamethazine, Sulfadimethoxine, Sulfapiradine, Sulfathiazol	Bovine	600	224	0
Mexico	Antibiotics	Chloramphenicol	Bovine	150	53	6 11%
Mexico	Benzimidazoles	Albendazole, Ofbendazole, Thiabendazole, Cambendazole, Mebendazole, Febendazole	Bovine	640	0	0
Mexico	Heavy Metals	Copper, Cadmium, Lead, Arsenic, Mercury	Bovine	2250	489	1

1993 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Ireland	Beta-Agonists	**Clenbuterol, Salbutamol**	Bovine	200	**2426**	**191**
Ireland	Beta-Agonists	Clenbuterol, Salbutanol	Ovine	50	50	0
Ireland	Estrogenic, Androgenic, Gestagenic	Trenbolone	Equine	10	200	0
Ireland	Estrogenic, Androgenic, Gestagenic	Trenbolone	Ovine	200	200	0
Ireland	Estrogenic, Androgenic, Gestagenic	Trenbolone	Porcine	250	313	0
Ireland	Estronic, Androgenic, Gestagenic	Trenbolone, Zeranol	Bovine	1666	2843	63
Ireland	Hormones	Estradiol, Progesterone, Testosterone	Bovine	300	731	0
Ireland	Inhibitory Substances	Carbadox, Sulfamethazine, Nitrofurans	Bovine	210	70	0
Ireland	Inhibitory Substances	Chloramphenicol, Betalactams, Amno Glycosides, Marolides	Bovine	3150	4558	34

1993 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Ireland	Inhibitory Substances	Chloramphenicol, Betalactams, Tetracyclines, Amino Glycosides, Marolides	Equine	60	460	2
Ireland	Inhibitory Substances	Chloramphenicol, Betalactams, Tetracyclines, Amno Glycosides, Macrolides	Ovine	300	460	2
Ireland	Inhibitory Substances	Chloramphenicol	Ovine	30	0	0
Ireland	Inhibitory Substances	Carbadox, Sulphamethazine, Nitrofurans	Ovine	40	12	0
Ireland	Inhibitory Substances	Carbardox, Sulfamethazine, Nitrofurans	Porcine	280	739	21
Ireland	Inhibitory Substances	Chloramphenicol	Porcine	120	120	0
Ireland	Inhibitory Substances	Chloramphenicol, Betalactams, Tetracyclines, Amino Glycosides, Macrolides	Porcines	4528	5815	273

1993 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Ireland	Trace Elements	Arsenic, Cadmium, Lead	Ovine	60	264	0
Ireland	Trace Elements	Arsenic, Cadmium, Lead	Porcine	120	648	0
Ireland	Various other Hormones incl.	Nortestosterone, Methyltestosterone, Megestrol Acetate, Chlormedirone Acetate	Bovine	890	1326	22
Ireland	Various other Hormones incl.	Nortestosterone, Methyltestosterone, Megastol Acetate, ChlormadironeAcetate, Medroxy Progesterone	Ovine	70	74	0
Ireland	Various other Hormones incl.	Nortestosterone, Methyltestosterone, Megastrol Acetate, ChlormadironAcetate, Medroxy Progesterone	Porcine	70	71	0
Israel	Drugs	Antibiotics, Chloramphenicol, Sulfonamides, Furazolidone, Nitrofurazone	Avian	1500	1344	30

Mr. TOWNS. Your report states that USDA does not test imported meat for heavy metals even though exporting countries have reported finding high instances of heavy metals in excess of their domestic standards. Can you provide a specific example? What countries and compounds are you talking about?

Mr. ZADJURA. Sure. I can give you several of them. In various points in time in 1989, 1990, 1991, 1992, and 1993, New Zealand, for example, reported violations of between 3 and 100 percent of their test samples for cadmium, mercury, and zinc.

Denmark in 1992 reported 11 percent for cadmium, lead, mercury, chromium, nickel, selenium.

Australia has reported in 1991, rates up to 53 percent of violations of their own standards for arsenic, cadmium, mercury, copper, lead, selenium.

Argentina in 1989, 1990, has found violations in their own testing of 10 to 41 percent for lead, cadmium, mercury and arsenic.

There are others.

Mr. TOWNS. I ask unanimous consent to enter into the record documents obtained from the subcommittee from USDA which show that foreign countries are reporting levels of heavy metals in their meat and poultry.

[The information referred to follows:]

Department of Primary Industries and Energy

T87/1085
0326E

AUSTRALIA

1 December 1987

Ms Patricia Stolfa
Deputy Administrator
International Programmes
USDA FSIS
WASHINGTON DC 20250

Dear Ms Stolfa

Included with this letter is Australia's response to the US Residue Programme Questionnaire.

You will note that a considerable number of pages are devoted to Australia's approach to the problem of meat residues that are not covered specifically in the questionnaire. I believe this approach is highly relevant and an integral part of our reactions to the residue problem overall. Consequently we have addressed this in the introductory pages of our answers to the questionnaire.

There are three annexes referred to in the text. These are

Annex D - Requirements for clearance of Agricultural Chemicals

Annex E - Requirements for clearance of Veterinary Chemicals

Annex F - Instructions to the field.

Also attached is a copy of CALM (Computer Aided Livestock Marketing) which is also referred to in the text.

We would be happy to provide any further information you may require.

Yours sincerely

PH Langhorne
Director
Australian Quarantine & Inspection Service

U.S. Residue Programme

Questionnaire

Australian Answers

ANNEX C

POTENTIAL ENVIRONMENTAL CONTAMINANTS OF TISSUES OF FOOD-PRODUCING ANIMALS

. Aflatoxins

- Aflatoxins may occur in livestock feeds when these are prepared or stored under adverse or unsuitable conditions.
- Ingestion of these feedstuffs may lead to the occurrence of residues in animal tissues and milk.

. Aldrin/dieldrin

- Use of these persistent organochlorine chemicals on food animals was banned over 20 years ago.
- Other agricultural uses have been recently terminated.
- Residues may occur in animal tissues as a result of exposure to an environment contaminated from past use.

. Arsenic

- Arsenic was used for many years as a dip to control external parasites of sheep and cattle. This was discontinued some years ago but environmental contamination from past use will remain.
- Some residues will occur as a result of the approved use of organic arsenical feed additives in pigs and poultry.

. Chlordane

- As for aldrin/dieldrin.

. Cadmium

- Seemingly high levels of cadmium have occurred from time to time in kidneys of sheep and cattle from certain areas of Australia. Other tissues do not show elevated levels.
- This is not associated with industrial contamination of the environment.
- It is possibly a physiological response to naturally occurring environmental cadmium.
- Investigations are continuing.

. 2,4-D

- The phenoxy herbicides do not concentrate in food chains and do not persist from year to year in crop or pasture lands.

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Argentina	Byphenyl Polychlorides	PCBs	Bovine	67	126529	0
Argentina	Chloramphenicol	Chloramphenicol	Equine	100	0	0
Argentina	Chloramphenicol	Chloramphenicol	Ovine	100	0	0
Argentina	Estrogenic Substances	Zeranol	Bovine	250	0	0
Argentina	Estrogenic Substances	Zeranol	Equine	25	0	0
Argentina	Estrogenic Substances	Zeranol	Ovine	25	0	0
Argentina	Heavy Metals	Lead, Cadmium, Mercury, Arsenic	Bovine	150	2614	1079
Argentina	Heavy Metals	Lead, Cadmium, Mercury, Arsenic	Equine	25	0	0
Argentina	Heavy Metals	Lead, Cadmium, Mercury, Arsenic	Ovine	25	0	0
Argentina	Organochloride Pesticides	HCB, HCH, Lindane, HPT, HPX, ALD, DLD, END, DDT & Metab., CLD, Mirex, Methoxychlor Toxaphene	Bovine	0	1391034	6684

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Belize	Hormones	DES	Bovine	20	0	0
Belize	Organochlorides	Organochlorides	Bovine	365	60	2
Belize	Organochlorides	PCB's	Bovine	365	60	0
Belize	Organophosphates	Organophosphates	Bovine	18	3	0
Belize	Sulfonamides	Sulfamethazine	Bovine	12	0	0
Belize	Trace Elements	Arsenic, Mercury, Lead, Cadmium	Bovine	18	2	0
Canada	Antibiotics	Antibiotics	Avian	0	467	0
Canada	Antibiotics	Antibiotics	Bovine	13980	19136	0
Canada	Antibiotics	Antibiotics	Caprine	0	12	0
Canada	Antibiotics	Antibiotics	Equine	900	879	0
Canada	Antibiotics	Antibiotics	Ovine	0	176	0
Canada	Antibiotics	Antibiotics	Porcine	9660	21294	7
Canada	Arsenic & Heavy Metals	Arsenic & Heavy Metals	Avian	620	595	4

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Canada	Arsenic & Heavy Metals	Arsenic & Heavy Metals	Equine	600	654	109
Canada	Beta-Agonists	Clenbuterol	Bovine	0	49	0
Canada	Beta-Agonists	Clenbuterol	Porcine	0	47	0
Canada	Beta-Blockers	Beta-Blockers	Bovine	50	0	0
Canada	Carbadox	Carbadox	Porcine	920	408	3
Canada	Chloramphenicol	Chloramphenicol	Bovine	300	311	0
Canada	Chloramphenicol	Chloramphenicol	Porcine	150	150	0
Canada	Clopidol	Clopidol	Avian	150	166	0
Canada	Coccidiostat Screen	Coccidiostat Screen	Avian	100	730	0
Canada	Coccidiostat Screen	Coccidiostat Screen	Bovine	50	121	0
Canada	Decoquinate	Decoquinate	Avian	150	60	0
Canada	Decoquinate	Decoquinate	Bovine	50	121	0
Canada	Dimetridazole	Dimetridazole	Avian	75	42	0
Canada	Dimetridazole	Dimetridazole	Porcine	300	303	0

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Canada	Heavy Metals	Heavy Metals	Bovine	450	594	54
Canada	Heavy Metals	Heavy Metals	Ovine	100	121	8
Canada	Heavy Metals	Heavy Metals	Porcine	360	470	40
Canada	Ivermectin	Ivermectin	Bovine	200	219	0
Canada	Ivermectin	Ivermectin	Ovine	50	0	0
Canada	Ivermectin	Ivermectin	Porcine	150	170	1
Canada	MGA	MGA	Bovine	50	75	0
Canada	MGA	MGA	Equine	50	50	0
Canada	MGA	MGA	Porcine	50	55	0
Canada	Natural Hormones	Natural Hormones	Bovine	20	0	0
Canada	Nortestosterone	Nortestosterone	Bovine	20	0	0
Canada	PCB	PCB	Avian	540	665	0
Canada	PCB	PCB	Bovine	600	1033	2
Canada	PCB	PCB	Equine	300	328	1

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Canada	PCB	PCB	Ovine	150	144	0
Canada	PCB	PCB	Porcine	450	553	0
Canada	PCP	PCP	Avian	200	245	0
Canada	PCP	PCP	Bovine	300	348	7
Canada	PCP	PCP	Porcine	750	706	88
Canada	Pesticides	Pesticides	Avian	540	665	0
Canada	Pesticides	Pesticides	Bovine	600	1033	2
Canada	Pesticides	Pesticides	Equine	300	328	1
Canada	Pesticides	Pesticides	Ovine	150	144	0
Canada	Pesticides	Pesticides	Porcine	450	553	0
Canada	Sufonamides		Avian	200	256	0
Canada	Sulfonamides		Bovine	600	795	10
Canada	Sulfonamides		Ovine	50	138	0
Canada	Sulfonamides		Porcine	66970	64445	433

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
France	Heavy Metals	Lead, Cadmium	Porcine	540	133	3
France	Hormones	DES, Estradiol, Trenbolone, Nortestosterone	Bovine	22435	10369	400
France	PCB's	PCB's	Avian	65	78	0
France	PCB's	PCB's	Bovine	200	1255	0
France	PCB's	PCB's	Ovine	100	680	0
France	Pesticides OC	HCB, HCB 1, B, R, Endrin, HE, Aldrin, Dieldrin, DDE, TDE, DDT	Avian	65	780	0
France	Pesticides OC	HCB, HCB L, B, R, HE, Dieldrin, DDE, TDE, DDT	Bovine	200	11295	0
France	Pesticides OC	HCB, HCB L, B, R, HE, Dieldrin, DDE, TDE, DDT	Ovine	100	6120	0
France	Pesticides OP	Dibrom, Malathion, Ethyl Parathion, Methyl Parathion, Mevinphos, Fenchlorphos, Ethion, Methation	Avian	65	702	0

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Hungary	Sulfonamides	Sulfamethazine, HPTLC	Bovine	50	477	0
Hungary	Sulfonamides	Sulfamethazine, HPTLC	Porcine	440	1983	0
Hungary	Thyrostatics	Thiouracil, 6-Methyl-2-Thiouracil, 6-Propyl-2-Thiouracil, Tapazole	Bovine	608	127	0
Hungary	Thyrostatics	Thiouracil, 6-Methyl-2-Thiouracil, 6-Propyl-2-Thiouracil, Tapazole	Ovine	240	0	0
Hungary	Thyrostatics	Thiouracil, 6-Methyl-2-Thiouracil, 6-Propyl-2-Thiouracil, Tapazole	Porcine	1648	338	0
Hungary	Trace Elements	Arsenic, Cadmium, Chromium, Mercury, Lead, Zinc	Avian	1410	0	0
Hungary	Trace Elements	Arsenic, Cadmium, Copper, Mercury, Lead, Zinc	Bovine	576	672	31
Hungary	Trace Elements	Arsenic, Cadmium, Copper, Mercury, Lead, Zinc	Ovine	72	0	0

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
New Zealand	Endoparasitic	Levamisole	Porcine	300	26	0
New Zealand	Endoparasitic	Ivermectin	Porcine	300	62	0
New Zealand	Endoparasitic Substances	Oxfendazole, Mebendazole, Fenbendazole, Febantel	All	300	0	0
New Zealand	Endoparasitic Substances	Ivermectin	Ovine	300	53	0
New Zealand	Endoparasitic Substances	Levamisole	Ovine	300	167	0
New Zealand	Endoparasitic Substances	Benzimidazoles, Albendazole	Ovine	300	694	3
New Zealand	Heavy Metals	Cadmium, Zinc	Bovine	300	333	46
New Zealand	Heavy Metals	Cadmium, Zinc	Caprine	0	1	0
New Zealand	Heavy Metals	Cadmium, Zinc	Equine	300	28	25
New Zealand	Heavy Metals	Cadmium, Zinc	Ovine	300	609	71
New Zealand	Heavy Metals	Mercury	Porcine	300	1051	66
New Zealand	Heavy Metals	Arsenic	Porcine	300	0	0

1990 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Poland	Contaminants: Organophosphorous Compounds	Ronnel, Trichlorfon, Fenthion, Malathion, Parathion, Met. Parath., Chloropyrifos	Bovine	400	215	0
Poland	Contaminants: Organophosphorous Compounds	Ronnel, Trichlorfon, Fenthion, Malathion, Parathion, Met. Parath., Chloropyrifos	Equine	400	0	0
Poland	Contaminants: Organophosphorous Compounds	Ronnel, Trichlorfon, Fenthion, Malathion, Parathion, Met. Parath., Chloropyrifos	Ovine	400	0	0
Poland	Contaminants: Organophosphorous Compounds	Ronnel, Trichlorfon, Fenthion, Malathion, Parathion, Met. Parath., Chloropyrifos	Porcine	400	664	0
Poland	Heavy Metals	Cadmium	Bovine	600	2260	27
Poland	Heavy Metals	Lead	Bovine	600	2260	3
Poland	Heavy Metals	Arsenic	Bovine	600	2257	0
Poland	Heavy Metals	Mercury	Bovine	600	2260	0

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Australia	Chloramphenicol	Chloramphenicol	Avian	200	163	0
Australia	Chloramphenicol	Chloramphenicol	Bovine	300	314	0
Australia	Chloramphenicol	Chloramphenicol	Equine	300	249	0
Australia	Chloramphenicol	Chloramphenicol	Ovine	300	231	0
Australia	Chloramphenicol	Chloramphenicol	Porcine	300	264	0
Australia	Closantel	Closantel	Ovine	300	240	0
Australia	Cyromazine	Cyromazine	Bovine	300	0	0
Australia	Cyromazine	Cyromazine	Ovine	300	291	1
Australia	Dimetridazole	Dimetridazole	Avian	200	168	0
Australia	Dimetridazole	Dimetridazole	Porcine	300	135	0
Australia	Heavy Metals	Cadmium, Copper, Lead, Mercury, Selenium, Zinc, Arsenic	Bovine	1200	1590	59
Australia	Heavy Metals	Cadmium, Copper, Lead, Mercury, Selenium, Zinc, Arsenic	Equine	300	142	75

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Australia	Heavy Metals	Cadmium, Copper, Lead, Mercury, Selenium, Zinc, Arsenic	Ovine	1200	959	106
Australia	Heavy Metals	Cadmium, Copper, Lead, Mercury, Selenium, Zinc, Arsenic	Porcine	600	623	45
Australia	Ivermectins	Avermectins	Bovine	300	413	3
Australia	Ivermectins	Avermectins	Ovine	300	392	0
Australia	Ivermectins	Avermectins	Porcine	300	372	0
Australia	Levamisole	Levamisole	Bovine	300	288	0
Australia	Levamisole	Levamisole	Ovine	300	235	0
Australia	Levamisole	Levamisole	Porcine	300	252	0
Australia	Organochlorines	(Includes PCB's)	Avian	600	369	0
Australia	Organochlorines	(Includes PCB's)	Bovine	5000	7346	3
Australia	Organochlorines	(Includes PCB's)	Caprine	300	154	0
Australia	Organochlorines	(Includes PCB's)	Equine	300	352	0

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Canada	Chlorinated Hydrocarbon Pesticides	Any & PCB's	Equine	600	301	2
Canada	Chlorinated Hydrocarbon Pesticides	Any & PCB's	Ovine	300	176	0
Canada	Chlorinated Hydrocarbon Pesticides	Any & PCB's	Porcine	900	507	0
Canada	Gestagenic Substances	Melengestrol Acetate	Bovine	100	51	0
Canada	Gestagenic Substances	Melengestrol Acetate	Equine	200	46	0
Canada	Gestagenic Substances	Melengestrol Acetate	Porcine	200	51	0
Canada	Heavy Metals	Arsenic, Cadmium, Mercury, Lead, Zinc	Avian	3175	2906	0
Canada	Heavy Metals	Arsenic, Cadmium, Mercury, Lead, Zinc	Bovine	2250	2520	53
Canada	Heavy Metals	Arsenic, Cadmium, Mercury, Lead, Zinc	Equine	3000	3450	34

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Canada	Heavy Metals	Arsenic, Cadmium, Mercury, Lead, Zinc	Ovine	500	566	2
Canada	Heavy Metals	Arsenic, Cadmium, Mercury, Lead, Zinc	Porcine	1800	1840	56
Canada	Natural Hormones	Estradiol, Progesterone, Testosterone	Bovine	40	0	0
Canada	Organophosphate Pesticides	Any	Avian	1170	594	0
Canada	Organophosphate Pesticides	Any	Bovine	1500	657	0
Canada	Organophosphate Pesticides	Any	Equine	600	301	0
Canada	Organophosphate Pesticides	Any	Ovine	300	176	0
Canada	Organophosphate Pesticides	Any	Porcine	900	507	0
Canada	Other Antimicrobials	Carbadox, Dimetridazole	Avian	150	72	0
Canada	Other Antimicrobials	Carbadox, Dimetridazole	Porcine	1580	843	9

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Canada	Other Contaminants	PCP	Avian	425	208	3
Canada	Other Contaminants	PCP	Bovine	600	301	4
Canada	Other Contaminants	PCP	Porcine	1500	750	41
Canada	Other Estrogenic Substances	Zeranol	Bovine	1350	615	0
Canada	Other Estrogenic Substances	Zeranol	Equine	200	46	0
Canada	Other Estrogenic Substances	Zeranol	Porcine	200	51	0
Canada	Stilbenes	DES, Hexestrol, Dienestrol	Bovine	1350	615	0
Canada	Stilbenes	DES, Hexestrol, Dienestrol	Equine	200	46	0
Canada	Stilbenes	DES, Hexestrol, Dienestrol	Porcine	200	51	0
Canada	Sulfonamides	Any	Avian	425	236	0
Canada	Sulfonamides	Any	Bovine	1200	917	29

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Czechoslovakia	Hormones		Bovine	100	152	0
Czechoslovakia	Hormones		Porcine	200	92	0
Czechoslovakia	Organophosphates		Bovine	100	0	0
Czechoslovakia	Organophosphates		Porcine	180	0	0
Czechoslovakia	PCB		Bovine	100	450	0
Czechoslovakia	PCB		Porcine	300	49	0
Czechoslovakia	PCB's	PCB's	Avian	0	122	0
Czechoslovakia	Sulfonamides		Bovine	100	49	0
Czechoslovakia	Sulfonamides		Porcine	100	80	0
Czechoslovakia	Trace Elements	Trace Elements	Avian	0	230	0
Czechoslovakia	Trace Elements		Bovine	200	1917	43
Czechoslovakia	Trace Elements		Porcine	300	940	0
Denmark	Antibacterial Substances	Chloramphenicol	Bovine	150	150	0
Denmark	Antibacterial Substances	Nitrofurans	Bovine	100	99	0

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Hungary	Organophosphates	Diazinon, Methylparathion, Phenitrothion, Ronnel, Parathion, Ethion,Bromophos, Malathion, Phenthion	Ovine	168	0	0
Hungary	Organophosphates	Diazinon, Methylparathion, Phenitrothion, Ronnel, Parathion, Ethion,Bromophos, Malathion, Phenthion	Porcine	5908	462	0
Hungary	Sulfonamides	Sulfamethazine	Avian	310	0	0
Hungary	Sulfonamides	Sulfamethazine	Bovine	157	294	0
Hungary	Sulfonamides	Sulfamethazine	Ovine	54	0	0
Hungary	Sulfonamides	Sulfamethazine	Porcine	1348	2337	0
Hungary	Toxic and Trace Elements	Arsenic, Cadmium, Copper, Mercury, Lead, Zinc	Avian	1070	0	0
Hungary	Toxic and Trace Elements	Arsenic, Cadmium, Copper, Mercury, Lead, Zinc	Bovine	548	704	20

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Hungary	Toxic and Trace Elements	Arsenic, Cadmium, Copper, Mercury, Lead, Zinc	Ovine	58	0	0
Hungary	Toxic and Trace Elements	Arsenic, Cadmium, Copper, Mercury, Lead, Zinc	Porcine	2044	2502	52
Ireland	Estrogenic, Androgenic, Gestagenic	Estradiol, Progesterone, Testosterone	Bovine	300	594	0
Ireland	Estrogenic, Androgenic, Gestagenic	Zeranol, Trenbolone	Bovine	1753	5413	0
Ireland	Estrogenic, Androgenic, Gestagenic	Zeranol, Trenbolone	Equine	5	81	0
Ireland	Estrogenic, Androgenic, Gestagenic	Zeranol, Trenbolone	Ovine	40	81	0
Ireland	Estrogenic, Androgenic, Gestagenic	Zeranol, Trenbolone, Estradiol, Progesterone, Testosterone	Porcine	105	49	0

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Ireland	Stilbenes	DES, Hexestrol, Dienestrol	Porcine	105	257	0
Ireland	Thyrostatics	Thiouracil, Methylthiouracil, Propylthiouracil, Dimethylthiouracil, Mercapto - Methylimidazole	Bovine	50	73	0
Ireland	Trace Elements	Arsenic, Cadmium, Lead	Bovine	300	150	0
Ireland	Trace Elements	Arsenic, Cadmium, Lead	Porcine	300	150	0
Israel	Antibiotics		Avian	100	105	24
Israel	Chloramphenicol		Avian	80	120	18
Israel	Chlorinated Hydrocarbons		Avian	60	58	0
Israel	Heavy Metals		Avian	236	681	27
Israel	Organophosphates		Avian	60	60	1
Israel	PCB's		Avian	60	40	0
Israel	Sulfonamides		Avian	80	77	1

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
New Zealand	Antimicrobials Drugs	Trimethoprim	Bovine	300	240	3
New Zealand	Antimicrobials Drugs	Sulfonamides	Bovine	2500	3299	3
New Zealand	Antimicrobials Drugs	Sulfonamides & Trimethoprim	Caprine	300	21	0
New Zealand	Antimicrobials Drugs	Sulfonamides & Trimethoprim	Equine	300	20	0
New Zealand	Antimicrobials Drugs	Sulfonamides & Trimethoprim	Ovine	300	68	0
New Zealand	Antimicrobials Drugs	Sulfonamides	Porcine	1200	1810	98
New Zealand	Beta blockers	Clembuterol	Bovine	600	431	0
New Zealand	Beta blockers	Clembuterol	Caprine	600	10	0
New Zealand	Beta blockers	Clembuterol	Equine	600	20	0
New Zealand	Beta blockers	Clembuterol	Ovine	600	40	0
New Zealand	Contaminants Heavy metals	Cd	Bovine	275	289	62

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
New Zealand	Contaminants Heavy metals	Cd	Equine	25	55	30
New Zealand	Contaminants Heavy metals	Cd	Ovine	200	475	76
New Zealand	Contaminants Heavy metals	Cd	Ovine	100	0	0
New Zealand	Ectoparasitic (Insect Growth Regulator)	Cyromazine	Bovine	300	108	0
New Zealand	Ectoparasitic (Insect Growth Regulator)	Cyromazine	Ovine	300	214	0
New Zealand	Endoparasiticides	Alendazole(Sulphone), Febantel, Febendazole, Mebendazole, Morantel	Avian	300	0	0
New Zealand	Endoparasiticides	Levamisole	Avian	300	0	0
New Zealand	Endoparasiticides	Ivermectin	Bovine	460	468	29
New Zealand	Endoparasiticides	Levamisole	Bovine	300	182	0
New Zealand	Endoparasiticides	Albendazole(Sulphone), Febantel, Febendazole, Mebendazole, Morantel	Bovine	300	181	1

1991 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
New Zealand	Heavy metals	Pb	Bovine	300	289	0
New Zealand	Heavy metals	Pb	Equine	300	30	0
New Zealand	Heavy metals	Hg	Porcine	300	351	45
New Zealand	Herbicides	2,4-D, 2,4-DB, 2,4,5-T	Caprine	100	0	0
New Zealand	Herbicides	2,4-D 2,4-DB 2,4,5-T	Ovine	200	203	0
New Zealand	Macrolides	Tylosin, Erythromycin, Oleandomycin, Spiramycin	Porcine	300	250	0
New Zealand	Organo Phosphates and Carbamates	30 Compounds	Avian	300	0	0
New Zealand	Organo Phosphates and Carbamates	30 Compounds	Bovine	300	82	0
New Zealand	Organo Phosphates and Carbamates	30 Compounds	Caprine	300	11	0
New Zealand	Organo Phosphates and Carbamates	30 Compounds	Equine	300	5	0
New Zealand	Organo Phosphates and Carbamates	30 Compounds	Ovine	300	227	0

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COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Poland	Other Estrogenics	Zeranol	Bovine	400	318	0
Poland	PCB's	PCB's	Equine	0	16	0
Poland	Stilbenes	DES, DIE, HEX	Bovine	400	318	0
Poland	Sulfonamides	Sulfadimidine and others	Bovine	200	280	0
Poland	Sulfonamides		Equine	0	22	0
Poland	Sulfonamides	Sulfadimidine and others	Porcine	200	752	0
Poland	Sympathomimetics	Clenbuterol, Salbutamol	Bovine	50	100	0
Poland	Sympathomimetics	Clenbuterol, Salbutamol	Porcine	50	100	0
Poland	Thyrostatics	Tapazole	Bovine	200	203	0
Poland	Trace Elements	Mercury, Cadmium, Lead, Arsenic	Bovine	800	2169	5
Poland	Trace Elements	Mercury, Cadmium, Lead, Arsenic	Equine	0	135	0
Poland	Trace Elements	Mercury, Cadmium, Lead, Arsenic	Porcine	1800	14492	9
Romania	Antibiotics	Chlortetracycline, Hydrochloride, Oxytetracycline, Penicillin, Streptomycin, Tetracycline, Tylosin	Bovine	4500	3558	0

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COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Yugoslavia	Trace Elements	Arsenic, Cadmium, Mercury, Lead	Bovine	280	73	0
Yugoslavia	Trace Elements	Arsenic, Cadmium, Mercury, Lead	Porcine	280	176	3

1992 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Australia	Antimicrobials	Nitrofurans	Bovine	300	241	0
Australia	Antimicrobials	General Screen	Bovine	1200	2096	0
Australia	Antimicrobials	Chloramphenicol	Bovine	300	272	0
Australia	Antimicrobials	General Screen	Equine	300	286	0
Australia	Antimicrobials	Sulfonamides	Porcine	600	1112	0
Australia	Antimicrobials	Nitrofurans	Porcine	300	250	0
Australia	Antimicrobials	General Screen	Porcine	1200	1611	0
Australia	Heavy Metals	Mercury, Lead, Cadmium, Zinc, Copper, Selenium, Arsenic	Bovine	1200	1293	1290
Australia	Heavy Metals	Mercury, Lead, Cadmium, Zinc, Copper, Selenium, Arsenic	Equine	300	254	254
Australia	Heavy Metals	Mercury, Lead, Cadmium, Zinc, Copper, Selenium, Arsenic	Ovine	1200	989	989
Australia	Heavy Metals	Mercury, Lead, Cadmium, Zinc, Copper, Selenium, Arsenic	Porcine	600	626	626

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COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Czech Republic	Hormones		Bovine	100	110	0
Czech Republic	Hormones		Porcine	200	111	0
Czech Republic	Organophosphates	Organophosphates	Bovine	100	630	0
Czech Republic	Organophosphates	Organophosphates	Porcine	180	0	0
Czech Republic	PCB's	PCB's	Bovine	100	763	0
Czech Republic	PCB's	PCB's	Porcine	300	300	0
Czech Republic	Sulfonamides	Sulfonamides	Bovine	100	96	0
Czech Republic	Sulfonamides	Sulfonamides	Porcine	100	96	0
Czech Republic	Trace Elements		Bovine	200	2172	0
Czech Republic	Trace Elements		Porcine	300	1995	24
Denmark	Antibacterial Substances	Nitrofuranes	Bovine	0	298	0
Denmark	Antibacterial Substances	Antibiotics	Bovine	0	2393	1
Denmark	Antibacterial Substances	CAP	Bovine	0	150	0

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COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
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COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Denmark	Chlorinated Hydrocarbons	Aldrin, DDD-p,p, DDE-p,p, DDT-p,p, Dieldrin, Endrin, Lindane, Alfa-HCH, Beta-HCH, Heptachlorepoxide	Bovine	120	121	0
Denmark	Chlorinated Hydrocarbons	Aldrin, DDD-p,p, DDT-p,p,DDE-p,p, Dieldrin, Endrin, Alfa-HCH, Beta-HCH, Lindane, Heptachlorepoxide	Porcine	120	118	0
Denmark	Heavy Metals	Cadmium, Lead, Mercury, Chromium, Nickle, Selenium	Bovine	100	100	11
Denmark	Heavy Metals	Cadmium, Lead. Mercury, Chromium, Nickle, Selenium	Porcine	100	0	0
Denmark	PCB's	PCB's	Bovine	120	121	0
Denmark	PCB's	PCB's	Porcine	120	118	0
Denmark	Substances with Hormonal Effect	Trenbolone, Zeranol, Progesterone, Testosterone, Estradiol-17-B, Medroxyprogesteronacetate	Bovine	0	1468	0

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COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Ireland	Trace Elements	Arsenic, Cadmium, Lead, Mercury	Ovine	30	384	0
Ireland	Trace Elements	Arsenic, Cadmium, Lead, Mercury	Porcine	120	552	0
Ireland	Tranquilizers	Azaperone, Propylpromazin, Carazolol	Bovine	10	0	0
Ireland	Tranquilizers	Azaperone, Propylpromazin, Carazolol	Porcine	40	50	0
Israel	Coccidiostats	Furazolidone	Avian	60	102	0
Israel	Coccidiostats	Nitrofurazone	Avian	60	110	0
Israel	Drugs	Antibiotics	Avian	200	364	22
Israel	Drugs	Chloramphenicol	Avian	200	430	18
Israel	Drugs	Sulfonamides	Avian	100	208	13
Israel	Environmental Pollutants	Heavy Metals	Avian	120	246	0
Israel	Environmental Pollutants	PCB's	Avian	60	46	0

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COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
New Zealand	Chloramphenicol		Porcine	300	48	0
New Zealand	Contaminants: Heavy Metals	Cadmium	Equine	150	154	154
New Zealand	Contaminants: Heavy Metals	Selenium	Ovine	300	303	0
New Zealand	Contaminants: Heavy Metals	Cadmium	Ovine	150	151	0
New Zealand	Contaminants: Heavy Metals	Mercury	Porcine	300	871	108
New Zealand	Flukicides	Nitroxynil	Bovine	350	205	0
New Zealand	Flukicides	Nitroxynil	Bovine	350	205	0
New Zealand	Flukicides	Nitroxynil	Ovine	350	106	0
New Zealand	Flukicides	Nitroxynil	Porcine	350	45	0
New Zealand	Insect Growth Regulator	Cyromazine	Ovine	300	304	0
New Zealand	Macrolides	Tylosin, Erythromycin, Oleandomycin, Spiramycin	Bovine	300	203	0

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COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
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COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Poland	Chlorinated Hydrocarbons	DDT, Lindane, BHC, HCB, Metoxychlor, Aldrin, Endrin, Dieldrin, Heptachlor, Heptachlorepoxide	Porcine	600	933	0
Poland	Heavy Metals	Cadmium, Lead	Bovine	600	1420	6
Poland	Heavy Metals	Arsenic, Mercury	Bovine	300	1420	2
Poland	Heavy Metals	Arsenic, Mercury	Equine	25	0	0
Poland	Heavy Metals	Cadmium, Lead	Equine	50	0	0
Poland	Heavy Metals	Arsenic, Mercury	Porcine	500	2465	2
Poland	Heavy Metals	Cadmium, Lead	Porcine	1000	2465	1
Poland	Organophosphates	Ronnel, Trichlorfon, Fenthion, Malathion, Parathion, Diazinon, Dichlorvos, Fenitrothion	Bovine	400	100	0
Poland	Organophosphates	Ronnel, Trichlorfon, Fenthion, Parathion, Malathion, Diazinon, Dichlorvos, Fenitrothion	Equine	50	0	0

1992 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Romania	Sulfonamides	Dimetridazole	Bovine	300	1296	0
Romania	Sulfonamides	Sulfamethazine, Sulfamethine, Sulfathiazole, Sulfaquinoxaline	Porcine	600	5509	0
Romania	Sulfonamides	Dimetridazole	Porcine	600	0	0
Romania	Sulphites	Sulphites	Porcine	300	411	0
Slovenia	Anabolic Agents	DES	Bovine	0	78	0
Slovenia	Anabolic Agents	Hexestrol, Dienestrol, Trenbolone 17-beta, Estradiol, Zeranol, Testosterone, and Progesteron	Bovine	0	22	0
Slovenia	Chlorinated Hydrocarbons	Aldrin, Dieldrin, Alfa HCH, DDT, Endrin, Heptachlor, Lindane, Metoxychlor	Bovine	0	69	0
Slovenia	Heavy Metals	Lead	Bovine	0	91	0
Slovenia	Heavy Metals	Cadmium	Bovine	0	90	2

1992 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Uruguay	Chloramphenicol	Chloramphenicol	Bovine	80	84	0
Uruguay	Chlorinated Hydrocarbons	HCH, Lindane, Aldrin, Dieldrin, DDT	Bovine	100	818	0
Uruguay	Heavy Metals	Arsenic, Cadmium, Mercury, Lead	Bovine	90	72	1
Uruguay	Nitrofurans		Bovine	30	0	0
Uruguay	Organophosphates	Diazinon, Durban, Nexagan, Ethion, Parathion	Bovine	180	101	0
Uruguay	PCB's	PCB's	Bovine	100	818	0
Uruguay	Sulfonamides	Sulfamethazine	Bovine	90	94	0
Yugoslavia	Antibiotics	Chloramphenicol	Bovine	60	0	0
Yugoslavia	Antibiotics	Penicillin, Tetracycline, Oxytetracycline, Chlortetracycline, Streptomycin, Tylosin, Neomycin	Bovine	60	0	0
Yugoslavia	Antibiotics	Chloramphenicol	Porcine	150	0	0

September 20, 1994

NOTE: Data is not complete for the 1993 Residue Testing Results because (1) we have not received information from the following three countries (Canada, France, Slovenia), and (2) time has not permitted us to enter data on other missing countries.

1993 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Belgium	Thyrostatics	Thiouracil, Methylthiouracil, Propylthiouracil Tapazol, Phenylthiouracil	Porcine	285	0	0
Belgium	Tranquillizers	Azaperol, Azaperone, Acetylpromazine, Propiopromazine Chloorpromazine	Porcine	55	91	0
Brazil	Antibiotics	Penicillin, Tetracyline, Erythromycin, Neomycin, Oxytetracycline Chlortetracycline, Streptomycin	Bovine	300	303	1
Brazil	Chloramphenicol	Chloramphenicol	Bovine	300	316	0
Brazil	Chlorinated Hydrocarbon	Aldrin, BHC, Lindane, HCB, Dieldrin, Endrin, Heptaclor, Heptaclor Epoxido, DDT, Clordane, PCB's	Bovine	300	352	1
Brazil	Heavy Metals	Arsenic, Zinc, Lead, Cadmium, Copper	Bovine	300	360	11

1993 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Honduras	Neomycin		Bovine	57	57	0
Honduras	Organophosphates	Organophosphates	Bovine	30	28	0
Honduras	PCB's	PCB's	Bovine	7000	4725	27
Honduras	Species		Bovine	806	0	0
Honduras	Sulfonamides	Sulfonamides	Bovine	30	28	0
Honduras	Trace Elements	Arsenic	Bovine	30	30	0
Honduras	Trace Elements	Lead	Bovine	30	30	0
Honduras	Trace Elements	Mercury	Bovine	30	30	0
Honduras	Trace Elements	Cadmium	Bovine	30	30	0
Honduras	Trace Elements	Copper	Bovine	30	30	0
Hong Kong	Antibacterial Substances	Extraneous Antibacterial Substances	Avian	12	6	0
Hong Kong	Drugs	Sulfonamides	Avian	4	4	0
Hong Kong	Drugs	Decoquinate	Avian	4	4	0
Hong Kong	Drugs	Ipronidazole	Avian	4	4	0

1993 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Poland	Contaminants Chlorinated Hydrocarbons	DDT, Metabolites, Lindane, BHC, HCB, Metoxychlor, Aldrin, Dieldrin Endrin, Heptachlor, Epoxide	Bovine	400	524	0
Poland	Contaminants Chlorinated Hydrocarbons	DDT, Metabolites, Lindane, BHC, HCB, Metoxychlor, Aldrin, Dieldrin, Endrin, Heptachlor Epoxide	Equine	50	0	0
Poland	Contaminants Chlorinated Hydrocarbons	DDT, Metabolites, Lindane, BHC, HCB, Metoxychlor, Aldrin, Dieldrin Endrin, Heptachlor Epoxide	Porcine	600	957	0
Poland	Contaminants, Heavy Metals	HG X6	Bovine	300	1644	0
Poland	Contaminants, Heavy Metals	CD	Bovine	600	1644	12
Poland	Contaminants, Heavy Metals	PB X5	Bovine	600	1644	20
Poland	Contaminants, Heavy Metals	AS X7	Bovine	300	1644	0

1993 RESIDUE TESTING RESULTS
COUNTRIES ELIGIBLE TO EXPORT MEAT AND POULTRY PRODUCT
TO THE UNITED STATES

COUNTRY	COMPOUND GROUP	COMPOUNDS	SPECIES	SAMPLES PLANNED	SAMPLES ANALYZED	VIOLATIONS
Poland	Contaminants, Heavy Metals	CD	Equine	50	0	0
Poland	Contaminants, Heavy Metals	AS X7	Equine	25	0	0
Poland	Contaminants, Heavy Metals	PB X5	Equine	50	0	0
Poland	Contaminants, Heavy Metals	HG X6	Equine	25	0	0
Poland	Contaminants, Heavy Metals	PB X5	Porcine	1000	2942	3
Poland	Contaminants, Heavy Metals	CD	Porcine	1000	2942	3
Poland	Contaminants, Heavy Metals	AS X7	Porcine	500	2942	0
Poland	Contaminants, Heavy Metals	HG X6	Porcine	500	2942	3
Poland	Contaminats Organophorus Compounds	Ronnel, Trichlorfon, Fenthion, Malathion, Parathion, Metaparathion, Chloropyrifos, Liazinon	Bovine	400	225	0

Mr. TOWNS. Why doesn't USDA test imported meat and poultry for these unapproved compounds and heavy metals, and what are the implications to public health?

Mr. HARMAN. There is a definite focus on the domestic concerns. The drugs and pesticides are domestic concerns and there is a lack of focus on imported products.

There are also no standards for heavy metal, as Ed just mentioned, and laid out some of the heavy metals that have been discovered. There are no standards in this country for those heavy metals. And as a result, I understand that some of these countries have since stopped reporting those results of their own tests because there are no standards in this country.

Mr. ZADJURA. There is one exception. There are some standards for arsenic in meat and poultry.

Mr. TOWNS. At this time, I yield to the ranking member of the subcommittee, Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

Gentlemen, I think the chairman did an excellent job in asking a number of specific questions with respect to the focus of this hearing which is chemical residues. I would like to ask a few broader questions.

Since this is about the fifth hearing in a series of hearings this subcommittee has held, I wonder if you can succinctly give us a general idea, do you believe that generally speaking the food that is purchased by consumers in the United States is subject to a high level of confidence in its safety and purity?

I am not discounting if problems do exist, you understand. It only takes one case of poisoning for it to be a serious problem. I am trying to get an overview.

What is your view of the food supply in the United States?

Mr. HARMAN. As an analyst, that is a very difficult question to answer because, you know, there is just very little data to sustain any judgment about the overall safety. And of course you have to define what you mean by safety. What is safe? It is a relative term.

But I would have to say after 10 years of working in this area that overall, we certainly cannot say that the food supply is unsafe. It is very difficult, given all these studies, to say that it is absolutely safe, and I don't think that we are ever going to get to a condition of absolute safety. We are always going to have those risks. But overall, I haven't stopped eating yet, although I did weigh quite a bit more when I started this work.

Mr. SCHIFF. Do you get a little nervous if you are at the food store doing the family shopping?

Mr. ZADJURA. Occasionally.

Mr. HARMAN. Yes, I have to admit that I do approach it a little differently now than I did 10 years ago. But again I wouldn't—particularly as it deals with pesticides and chemical residues, there is a general feeling that that is not quite as serious as microbial, which I think is a very serious situation that needs to be addressed immediately.

But on the other hand, just because there are no dead bodies that are immediate, doesn't mean it is not just as serious. So I think these are all problems and I think the most serious problem is the concern of the consumer. If the consumer loses confidence,

whether it is safe or isn't safe, it is not going to make a whole lot of difference because they are going to put a lot of pressure on a lot of people to bring about change.

Mr. SCHIFF. You said in your opening statement, Mr. Harman, that for a long time—and I think you were speaking for the GAO also in this—you have advocated that the responsibilities for food inspection be give to one agency.

Mr. HARMAN. That is correct.

Mr. SCHIFF. Do have you a recommendation as to which agency or a new agency, or how would you approach that?

Mr. HARMAN. There are problems no matter which direction you go, both political problems as well as just logistical problems. I think the last time we were here we stated that probably the best way to go would be to try to create another single agency that would pull all of these things together, because it is not just the creation of a single agency that is going to solve the problem, but the system has to be reengineered, too, using that term that is very popular these days. But it does have to be reengineered. And there are problems moving it to FDA, and there are certainly problems putting it all under USDA with consumer confidence.

So, if we haven't as an agency come down in any particular position on this, but probably if pushed, we would argue for a single agency that is probably recreated out of all that exists now and not try to——

Mr. SCHIFF. In other words, at least as you could see it now, you would place the responsibility in an agency that doesn't presently exist.

Mr. HARMAN. That is right.

Mr. ZADJURA. I think we have taken the position that it should be an agency with a health-based focus so that there is at least one that might fit that bill.

Mr. SCHIFF. Well, let me say that I lean in that direction too. I have had some differences with some things that the U.S. Department of Agriculture has done lately, but I think that there is an internal conflict, regardless of which administration is in authority and regardless of who is secretary, when an agency is responsible for marketing our food products and ensuring the safety too, which, if they raise the alarm, could interfere with the marketing responsibility of the agency.

I see that as an eternal tug of war as long as both responsibilities remain with the U.S. Department of Agriculture. So I think placing the responsibility in a health-based organization is the way to go. And without meaning any offense to anyone at the U.S. Department of Agriculture.

I would like to ask you about one other matter, and once again I am speaking generally. I don't want to focus on any one industry or any one product in the question I am about to ask you. But you have spoken favorably in the past about the HACCP program, the hazard analysis critical control point program. That is a program which is intended to press more responsibility on the food manufacturers. I wonder if either of you could elaborate on that program a bit.

Mr. HARMAN. Well, what it does, it shifts the responsibility and the control, so to speak, to a prevention mode and sort of an after-

the-fact detection mode. And it sets it up in a way that you are looking at the whole process, not just the process within one—the manufacturer, but from the farm all the way to the table of the points where you are more likely to have contamination, where you are more likely—and that is scientifically determined—more likely to have contamination entering into the food supply. And then you monitor those points. And those are the points that you would try to reduce, even, the amount of contamination that may be occurring.

Mr. SCHIFF. That is an industry—we are promoting that as an industry policy as opposed to a government policy?

Mr. HARMAN. Well, it becomes a government policy in the sense that is the overall system that you are using. The government becomes part of that system in overseeing that system to make sure that it is working and that it is identifying those areas where improvements need to be made in the system as well as areas of contamination.

You wouldn't completely do away with end product testing and you wouldn't necessarily in USDA do away with necessarily all their inspectors on line because there are some situations where you need visual inspections.

Ed is punching me here.

Mr. ZADJURA. Could I give you an example which I would take from EPA's testimony. They are going to talk about the issue of the pesticides on oats that got into the cereal, "The misuse continued for more than a year in part because no system was in place at the industry level to monitor raw materials or finished food products."

Well, in fact no system is in place at Federal level either. And there is no monitoring and no requirement for this system.

The HACCP system that we have supported in the past and some agencies are moving to in some areas would, in fact, require that industry have such a system in place and that the Federal Government monitor it. So that we would start at food production and monitor all the way until it went to the consumer's table, as opposed to now, where we test at the end and we found this—the cereal maker didn't know about this for a year but neither did the Federal Government, despite the fact that they cite 85,000 tests and all this kind of stuff. It was basically luck that we found this at all.

Mr. SCHIFF. I am out of time but I think that is the point. I want to stress again since this has come up, that the particular misuse of the chemical was by a contractor that the cereal company was contracting with. They didn't know about it. And once they found out about it, took the product off the market.

But we do have to have a system that would detect—this may have even, I am not sure, but it may have been a total fraudulent effect. I don't want to get into that as much as a system has to be in place to detect anything that can go wrong anywhere in the system.

Mr. ZADJURA. Apparently, Mr. Schiff, the contractor did this to save money without telling the cereal maker, General Mills, I guess. But in effect this is where the system is inherently flawed. They are not required to have any system to go back and check on that contractor's actions, to monitor the raw materials or the fin-

ished product that they are getting, and the Federal Government doesn't monitor their system for doing that because in fact it doesn't exist and it is one of the flaws in the system.

Mr. HARMAN. I think you are going to hear a lot of support from what I have read of the other testimonies that other people are going to be presenting for the HACCP approach.

Mr. SCHIFF. Thank you, Mr. Chairman.

Mr. TOWNS. I yield to Congressman Mica.

Mr. MICA. Well, as you know, I am interested in the issue of risk and risk assessment, and I also have been trying to get the Congress to do something it usually doesn't do and that is to think about the cost and benefit of some of these regulations and attempt to monitor every single activity out there by looking at the most cost-effective means and the means that will ensure public health, safety, et cetera.

I want to take on a couple of questions of risk, and in particular I don't think people should be lulled into thinking that the government can ensure at every single stage the quality of food.

For example, in the instance that was just cited, if someone had sprayed, say, some type of toxic chemical in the truck that took this particular product to market, you can't have inspectors going out inspecting every transport that moves these items.

When it gets to the shelf, you have mom and pop grocery stores or you have large chains that have warehouses and you can't have someone running around doing a chemical analysis of every bug spray that has been sprayed in those stores.

Are some of these assumptions correct?

Mr. HARMAN. They are absolutely correct, Congressman, and I don't want to give the impression at all that we are advocating that kind of a system.

Mr. MICA. Well, again, it is the thing that we have been trying to get across. Let's look at where there is the most likelihood of some damage being done, concentrate our resources on those real risks and not make people jump through 1,000 hoops and swat at flies and miss the elephants as our policy has so often done in Washington.

I noted in your—let's see, page 5 it says, matters for congressional consideration. And that is really what we have to concentrate on here. Things that we can do from a practical standpoint.

On page 5 in your executive summary you said, "An industry-operated risk-based system that integrated residue prevention, detection, and quality control from the farm to the slaughter house established with FSIS assistance and oversight would be more effective than the current Federal program."

Can you take a moment and talk about the risk-based system that you see created that would be most effective, say, for residue prevention in the detection and quality control area? And also, do you have any specific legislative proposals that we could act on?

Mr. HARMAN. Let me just briefly say that this system, the HACCP system, is based on a risk assessment of where your key problems and areas of contamination may occur. And I will ask Ed to talk in a little bit more detail.

But also with respect to the specific legislative—the only legislation that we have worked with on a formal basis was on the Senate side with regard to meat and poultry. We have given some legislative language that was passed on to the administration in terms of changes in meat and poultry inspection.

Mr. MICA. Is the administration planning any recommendations to us or do you have any——

Mr. HARMAN. Yes, I believe they are.

Mr. MICA. What is the agenda for getting that to us?

Mr. HARMAN. I think Mr. Taylor could answer that in more detail, but as I understand it, they have taken their first steps to develop microbial testing and processes and procedures that will improve that area, which is of course the area of real critical concern right now.

But they are moving toward and advocating a HACCP type system and I think they will be advocating that type of legislation or the legislative changes that need to be made in order to allow them to do that.

Mr. MICA. Maybe you could comment and then I want to get to another area.

Mr. ZADJURA. Yes, this particular recommendation relates to FSIS's residue testing program, but we have a similar one in the overall report and we also have one that we have made several times to food safety in general.

A couple of things would occur. We would rank risks across food items, we would rank risk based on the potential things that could happen to those food items. For example, microbial contamination which produces immediate injury and death, and I know you sat in on the hearings related to E. coli and that would probably rank higher than chemical residues.

And then within each of those areas, companies would be required to look at their systems, their processes, their production practices to identify risk areas and design control systems. And to relate to an example you gave, if there was a risk of, say, the oats in this case being hauled in the truck that has been sprayed with a pesticide or carcinogen for some reason, then if that was identified as a potential risk they would have a control point that might require periodic sampling of these trucks to see whether or not they were being cleaned properly and stuff like that.

If spraying for bugs in a grocery store processing plant was a risk area, they would have to have a system that would be monitored to some extent by the Federal Government that establishes controls for that process to make sure, for example, that there isn't food present or food products or raw materials present when they are spraying.

And this, by the way, the example that you have cited are pretty germane because many times accidental spraying of grains or things like the oats, or deliberate spraying with the wrong chemical, are in fact what causes residue problems but no one is required to check or monitor that on a specific basis.

Mr. MICA. All the programs that you are talking about are domestic. Let me divert to the second half and we can get to some of your specific recommendations and I hope you provide them to the committee for legislative change.

But one of the things that has disturbed me and I am concerned about is that we are more and more in the international marketplace, and some of the things you describe may very well protect our consumers domestically, and maybe we do a half good job here in achieving those goals. But if you go to the market today, the goods are from all over the world.

Now we are opening up our markets with NAFTA and some of the other agreements. I got a tomato in Florida, I am not sure where it has been, what it has been sprayed with, and what residue is on it. You open a can of fish from some other place, you know, the other end of the world. You had an apple from New Zealand. God only knows what they do in New Zealand with their apples.

But what are we going to do? I mean, you can monitor some of what is going on here, but a wave of products are coming into this country with residues and chemicals that have been banned in this country for years. You have a tremendous potential for contamination and problems.

How do we do this? You certainly aren't going to inspect every Mexican transport or be out in the fields and see what they are doing to this product.

What kind of assurance do we have that there are some minimal protections in place? We could have pristine rules for the United States and be letting this stuff in and having problems that we don't even know about.

Mr. HARMAN. There is a lot of issues with the importation of food and what we require for testing and making sure that food is safe.

Right now, as far as we are concerned, it is not in as good a condition as the domestic program. But because we simply don't test for some things for imported food that they even banned——

Mr. MICA. So the consumer is at much more risk taking and consuming a foreign-produced product, say particularly vegetables and the things of that sort, than domestic. Is that correct?

Mr. HARMAN. Again, it depends on the systems and the processes that that foreign country has.

Mr. MICA. But you don't really have any way to monitor foreign production the way in which we are already monitoring our domestic production?

Mr. ZADJURA. No, we have even less control over foreign imports. It doesn't necessarily mean that they are more risky. Some of them may in fact be safer. And I know that FDA is working on an MOU with some countries related to some products. But clearly we can do more.

All countries exporting to the United States are required to meet our food safety standards. And, in fact, if we went to a risk-based HACCP standard that required them to have HACCP-type programs, they would have to do that and demonstrate it to us in order to have their product imported so that certainly would be helpful.

Mr. MICA. I think my time has expired. I want to get back to some other areas that continue in this line of questioning. But you still give me grave concern about products coming in. I think domestically we do a pretty good job, but I see more and more foreign products on our shelves and there is no assurance that in fact these

have met the same quality standards or inspection standards as domestically produced food.

Mr. ZADJURA. In many cases that is true.

Mr. TOWNS. The gentleman is right.

His time has expired. I call on Congressman Portman.

Mr. PORTMAN. Thank you, Mr. Chairman. Thanks for holding yet another hearing on food safety. I am sorry I was late. I had an unavoidable conflict, although I see that our side seems fairly well represented at this point.

I may be going over some points that the chairman has already gone over, so cut me short. My concern is in the area of restructuring.

I think in the hearing in May we discussed the issue of what makes the most sense in terms of food safety within the Federal Government. At that time, I questioned USDA officials. As I recall, they were not sympathetic to—at least that was my impression—the national performance review, NPR as opposed to NRP. And I found that rather surprising.

Maybe I was naive, because the Vice President in Reinventing Government has proposed that we move to one food safety agency and that it be in a health-based agency, namely FDA, that that was something that the administration would support. But apparently the administration does not support that at least consistently.

My question to you, having just read your report, is, are you concluding that one agency can, indeed handle all of the functions of food safety and that would include new functions that you suggest in your report?

Mr. HARMAN. Yes, we do.

Mr. PORTMAN. And are you saying, based on your research, that it should be the Food and Drug Administration or are you saying that it should be a new agency to be set up under the auspices of the HHS or a new agency or department? What is your recommendation in that regard?

Mr. HARMAN. We would argue for a new agency that is a health-based agency, which would imply it would be in some way shape or form tied into HHS.

Mr. PORTMAN. In doing so would you envision that many of the costs that are currently involved in food safety, both at USDA and at FDA and for that matter at EPA, would be cost savings that could be in turn shifted to this new department?

Mr. HARMAN. That is true. We have never done an analysis on that. It would depend on how you would structure it and what you would move into that agency. But there is a lot of duplication that could possibly be avoided.

At the same time, moving to a HACCP-type system could result in some cost savings. I know our big concern here is not a cost issue, as much as is the system really doing what it is supposed to be doing. And we see all kinds of inconsistencies and problems with this system that has evolved over the last 90 years or so. And it just needs to be revamped. But we think there would be opportunity for cost savings as part of doing that.

Mr. ZADJURA. We have said that shifting to either a single agency or of course there has been discussions of shifting it to FDA or some place within HHS, would not, in effect, let you do away with

the $500 million that FSIS spends on meat and poultry inspection. That there is so much that needs to be done, that the money and personnel and resources would have to be given to the new agency because there are a lot of things—as Mr. Mica alluded to, the foreign inspections. They are doing a better job domestically. There is so much that isn't being done now that there would probably not be any net cost savings. You would have to move the money and the personnel with it.

Mr. HARMAN. Again, it would depend on how you structure it. And we, as we have with USDA, hopefully would—if this committee would want us to do that, try to start developing some data bases which would give some analysis of what would happen to people. The others we would have to get into their personnel bases, but we could start thinking about doing that type of thing.

Mr. PORTMAN. I think that would be interesting to those of us who are concerned about food safety as well as the costs. You named a number of characteristics in the current system that are flawed and one is the duplicative nature of the programs. You talked about diffuse responsibilities and the inefficiencies in the current system.

The HACCP program as well could involve some cost savings if done properly and there would be some cost increases in increased monitoring and enforcement. And I think that would be interesting for those of us following that.

The FSIS program I think is coming to the floor in some form under agriculture reorganization this week or next. So I assume that debate will at least be on the House side this year, and further questions will be raised.

One quick question on the HACCP program before my time is up. It seems to me that there is a consensus that prevention, whether it is in health care or food safety, makes sense. That there are certain ways to do that within the current system through a voluntary program. And that the end product testing is not the most effective way to get at food safety.

My question to you is, have you analyzed what the costs are to industry to do the so-called voluntary program, which I guess some would argue isn't voluntary, in fact, it would be a program that would be mandated but it would be voluntary to the programs to undertake it in the sense that it would not be a Federal program; it would be a company program. And then if you could give us just a couple of thoughts on how industry has reacted to the HACCP program.

Mr. HARMAN. Let me first just say a few general things and Ed may have some specifics on costs. I know we haven't done anything in GAO on cost issues for industry. But industry is in the lead here, I think, right now with HACCP. I think they see this as a way to improve the quality of their products and the safety of their products.

And so in a lot of cases, and I know we have done work in the meat inspection, in the meat poultry area, and doing this work, we have found a number of industries that are already moving toward a HACCP-type system because that is a real advantage to them. And it could become a competitive advantage to them if they could work out a system that does this type of thing.

Ed might have some thought on the cost.

Mr. ZADJURA. I don't have great specific detail on the cost, but we did in earlier work on meat and poultry with microbial testing contacted about 140 plants of various sizes and found that half of them are doing microbial testing and that was because they considered it a high risk and they were trying to determine effects on their production cycle.

The industry groups told us they were supportive of it. Most of the industry groups we talked to were supportive of it. Many companies are out there doing it. And I can tell you one cereal maker that is taking an $82 million write-off wishes they had one and it would have probably cost them less than $82 million.

I can tell you a fast food hamburger chain that wishes they had a better one last year or 2 years ago. So while it would be some additional cost to industry, the costs probably pale in comparison to when your company is named as having an unregistered, unapproved pesticide on your cereal or when children die from eating your hamburgers. The costs pale by comparison.

Mr. PORTMAN. Thank you, Mr. Chairman.

Mr. TOWNS. Thank you very much, Mr. Portman.

Before we close, let me ask a couple of other things.

What happens when USDA finds a residue violation?

Mr. ZADJURA. Well, in the past, from 1989 to 1992 we basically found that not very much happens. For example, they reported 21,000 violations to FDA. Because of limited resources, FDA has only followed up on about 20 percent of them, and there were in that period, I believe, 15 actions taken. Most of the things that were done were warning letters that carried no penalty or fine.

Mr. TOWNS. Was anybody prosecuted?

Mr. ZADJURA. There was one prosecution in that period. And there is clearly a problem with repeat offenders.

Mr. TOWNS. You know——

Mr. SCHIFF. I am sorry, could you say that again?

Mr. ZADJURA. There is a problem with repeat offenders. Not only do they find sometimes as many as 4,000 violations annually, periodically some of these are from the same operation. For example, in 1992, while the number—the absolute number of repeat violators are down, the company at the top of the list had 65 residue violations. Clearly sending them letters is not doing any good.

There were others with 21, 18, 14. There are pages of those with more than one violation. And some of these—and if you want, I will give you an example or two—have been going on for years before anything was done.

Mr. TOWNS. In other words, there were more than 21,000 violations, but only 1 prosecution?

Mr. ZADJURA. There was only one prosecution. There were, I think, I believe 2 citations and 12 injunctions in that 4-year period from 1989 to 1992.

In addition, I think that, having looked at their testimony, FDA is going to say they are getting a lot stronger, because they are going after more injunctions. That happens to be 11 in 1994. And I know that 2 of those 11 involve producers that have been having problems for in one case 7 years and in another case 9 years and

have been repeatedly notified. They have been sent warning letters which they didn't respond to.

FDA and the States have gone in there and cited them over and over and demanded corrective actions. And after 9 years, and I couldn't count up the number of violations, they have asked Justice in August of this year for an injunction against one of them.

The other case has gone on for 7 years and they are just asking for an injunction now. So I would say that there is not a lot of clout.

Mr. TOWNS. Let me just say that that is very disturbing. And you can expect a formal request coming from this committee asking for the best way to consolidate various food programs, because we just can't continue to do business as usual.

You know, I know some things you can see right away, but when I think about all the others that you can't see right away because they cause cancer or we don't yet know about what effects they may cause—well, I am troubled. We need to become more aggressive and fix these fundamental flaws.

For a while we were talking about health care reform. We stopped talking about it, but I think that any kind of health care reform has to look at how to prevent illness because otherwise we wouldn't really be reforming health care.

So let me thank both of you for your testimony. We look forward to working with you, and you can expect our request.

Mr. MICA. Mr. Chairman, are you planning another round?

Mr. TOWNS. I had not planned to, but go ahead.

Mr. MICA. Just a couple of questions again that I didn't finish on.

Again, I am very concerned about the question of the increasing amount of imported food which is increasing in the supply of food that is available.

In your report out on page 57 it said, "Finally, U.S. Federal agencies have even less leverage in addressing the problem of imported foods. Consequently, chemicals that are of concern because they are used in exporting countries but not in the United States may be entering the domestic food supply."

So we have more food coming in from these foreign countries. And I venture to say that sometime in the last year, you have had Italian pasta.

Mr. ZADJURA. Last night.

Mr. MICA. Mexican tomatoes and Chilean grapes, South America and Central America, Europe, and we have less and less control over those areas. So this is a concern to me, and I am not sure if we are moving forward in the right direction.

Again, looking at some of the risks, we spend more time with the Federal agency which already has certain authority and is not, obviously, enforcing it and at the same time we have more food coming into our supply from other sources. We have less control over that. That is an area that I wanted to see addressed.

In a previous hearing I asked what we were doing to develop technologies to detect some of these residues, et cetera. That is sort of my windup question. I see the chairman squirming.

Are we doing anything in the technology development area? And I think when they came before us, the budget for this area had

very little recommended to assist us. Has there been an improvement or are we looking at technologies that can assist us in quick detection?

Mr. HARMAN. There are efforts going on in that area, but it is not nearly enough to deal with the volume of——

Mr. ZADJURA. It will never solve the problem. It is not the way to solve the problem. End product testing, besides being extremely costly, is generally destructive.

Mr. MICA. Also, we talked about microbial testing and things of that sort. Are they moving forward with developing better technologies there?

Mr. HARMAN. Yes, they are. They are attempting to do that. And you do need some of that technology in a HACCP-type system. And industry will need some of that technology in a HACCP-type system.

But regarding imports, we have done work on imports specifically in certain foreign countries and right now we have some work going on dealing with Chile and it depends on the country, I think, in terms of the safety. But there is a lot—not a lot, but there are pesticides other countries are using that are not approved in this country and they can get into here——

Mr. MICA. But there is in fact more risk for products coming in from these other countries which are arriving in larger numbers than risk from domestic——

Mr. ZADJURA. The violation rates, for example, for imported fruits and vegetables is, I think, in the neighborhood of 4 or 5 to up to 9 percent, depending on what vegetable and what you are checking it for compared to just a couple of percent for U.S. products.

Mr. MICA. Then the other area—I will end—one of your recommendations was having FSIS shift the primary responsibility for day-to-day residue prevention detection and control to the industry.

Mr. ZADJURA. Under Federal monitoring, under a Federal-approved system that they would monitor.

Mr. MICA. I don't have any problem with that. I think that is good. I am just concerned that we already have certain laws and controls and regulations and it doesn't sound like the enforcement record is very good. So if you have suggestions or recommendations on how we tighten up the enforcement end of this——

Mr. HARMAN. I think the chairman is right. We probably need to stand back and take a look at what all the laws would be affected by consolidation of the food safety Federal responsibilities into one agency. They are going to be substantial. And it is certainly not going to be an easy process.

But the other thing I might mention regarding the imports is that we are also recommending that the Congress at least consider—now there are issues that have to be dealt with. I know Food and Drug have raised some of these issues—but consider putting the same type of system on imported products as—fruits and vegetables, for example, that currently exist for meat and poultry where the systems that other foreign countries use have to be equivalent. And there is a decision made by USDA that those systems are equivalent for meat and poultry.

To consider that type of a system, which is really a HACCP-type system, if you go to HACCP here, they would have to have that type of a system. So that would increase your reliability. But there are some issues that have to be dealt with.

Mr. MICA. Thank you.

I thank the chairman, too, and I think we can work together in the next year and hopefully incorporate some of your recommendations to improve what we are doing.

Thank you.

Mr. TOWNS. Let me thank you, too. Thank you very much for your testimony. Thank you.

I would like to call the second panel to the table. Mike Taylor, Administrator of the Food Safety and Inspection Service.

Mr. TAYLOR. This is Dr. Richard Carnevale, Dr. John Prucha, and Dr. Bonnie Buntain.

Mr. TOWNS. Please come forward. It is the custom of this committee that we swear in all witnesses.

[Witnesses sworn.]

Mr. TOWNS. Please note that they have answered in the affirmative.

Take a seat.

Let me begin. Thank you, very much for being here, Mr. Taylor.

Before you begin, let me just say a few words. The subcommittee congratulates you on your appointment. As I said to you when I visited with you last week, we have heard great things about you and we wish you well.

As you know, this committee has been very critical of USDA's meat and poultry inspection programs, and I think rightfully so. Your appointment signals great promise that the Department may finally be moving in the right direction. In fact, today I signed on as a cosponsor to H.R. 5055, the administration's Pathogen Reduction Act. This bill begins to deal with the problems of microbial contamination which we have talked about in this subcommittee a great deal.

I commend President Clinton, Secretary Espy and you, Mr. Taylor, and your staff and everyone who participated in the formulation of this bill. And I urge my colleagues on both sides of the aisle to seriously consider this measure.

I plan to work with you to bring about the reform that is needed in our meat and poultry inspection program because our country needs it. Our consumers need it. And most of all, our children need it.

So I am not just going to stand and criticize. I plan to roll up my sleeves and work very closely with you to do everything that we can to make certain that the people are safe. And this is what we are talking about, from the field to the farm to the fork.

But also I want you to know, Mr. Taylor, that this subcommittee has some real concerns about the safety and labeling of meat and poultry products. As this hearing indicates, we will continue to vigorously exercise our oversight responsibilities to ensure that people are protected.

And may I conclude by saying that the full text of your statement that you submitted in writing will be included in the record,

if you would summarize in 5 minutes that would allow the Members to raise questions.

STATEMENT OF MICHAEL TAYLOR, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY DR. RICHARD CARNEVALE, ASSISTANT DEPUTY ADMINISTRATOR FOR SCIENCE AND TECHNOLOGY; DR. JOHN PRUCHA, DEPUTY ADMINISTRATOR FOR INTERNATIONAL PROGRAMS; AND DR. BONNIE BUNTAIN, TEAM LEADER, ANIMAL PRODUCTION FOOD SAFETY PROJECT, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Mr. TAYLOR. Thank you, Mr. Chairman. And let me thank you for your kind words, and in particular, for your cosponsorship of the Pathogen Reduction Act of 1994. This is a very important piece of legislation that will contribute greatly to our ability to deal with the foodborne illness problem in this country associated with meat and poultry products.

I am pleased, Mr. Chairman, to be before you to discuss USDA's problems to regulate and prevent illegal and unsafe chemical residues and contaminants from entering the Nation's meat and poultry supply.

I am accompanied by Dr. Richard Carnevale, who is Assistant Deputy Administrator for Science and Technology, Dr. John Prucha, Deputy Administrator for International Programs, and representing the Animal and Plant Health Inspection Service is Dr. Bonnie Buntain, who leads the Animal Production Food Safety Project.

Mr. Chairman, this is my first congressional hearing in my new role as Administrator of the Food Safety and Inspection Service. I entered this job with a full understanding of the challenges we face in building a system of meat and poultry inspection that lives up fully to its public health responsibilities and that meets the public's high expectations regarding the safety of the food supply.

Our job at FSIS is clear. We must build a system of inspection that capitalizes fully on what science and technology have to offer to reduce the risk of foodborne illness.

And who we work for is also clear: every person in this country who purchases or consumes a meat or poultry product relies on us to do the best job we can on their behalf. They, Mr. Chairman, are our constituency. To serve them well, we need to change. You, Mr. Chairman, know that.

The oversight hearings that have you held on our Federal food safety programs, backed up by the studies of the General Accounting Office, have played an important role in documenting the need for change in how Federal regulators approach their food safety responsibilities. I applaud your leadership.

As the efforts of this subcommittee have shown, it is time for a basic paradigm shift in food safety regulation. When it comes to chemical contaminants and microbial pathogens, it is no longer sufficient to rely solely on Federal inspectors to detect and correct problems after they occur. We need to move toward risk-based systems of preventive controls in which food manufacturers take responsibility for systematically preventing problems and Federal in-

spectors are able to verify and take actions to ensure that such systems are working effectively.

We plan to propose regulations this fall that would require all meat and poultry plants to adopt the system of prevention controls known as HACCP. HACCP is a widely accepted tool that, if properly implemented, will make food safer.

It is based on the simple premise that safety must be built into a food product at each step in the process rather than relying entirely on end product testing to detect and eliminate problems. HACCP plans must address all potential food safety hazards, including those posed by illegal chemical residues and contaminants.

Under HACCP, each plant will adopt appropriate controls to prevent harmful contamination and FSIS will inspect and conduct tests as needed to ensure those controls are working.

Let me emphasize one important point, Mr. Chairman. HACCP is not a substitute for careful Federal oversight of the safety of our Nation's food supply.

The public expects vigilance on our part and, in the case of meat and poultry inspection, increased efforts to reduce the risks of foodborne illness associated with microbial pathogens such as E. Coli 0157:H7 and Salmonella. We are making that effort.

HACCP will increase our ability to improve the safety of the food supply and protect public health. HACCP will also help ensure that imported meat and poultry products meet our food safety standards and legal requirements. As we move to HACCP, those that export to the United States will have to establish equivalent systems of preventive controls.

Mr. Chairman, the General Accounting Office has made a number of recommendations for improvement in our chemical residue program. We will consider all of them carefully and we will work with Mr. Harman and his colleagues at GAO so that we can benefit fully from the insights they have gained during their study.

We will be focusing particularly on how we can shape the program to support our transition to HACCP. For example, we do need to better target our chemical evaluation system to provide sound guidance to companies on the hazard analysis component of their HACCP plans. We need to target chemicals that have the greatest potential to result in violative residues or pose a public health problem.

Finally, Mr. Chairman, I want to stress how important it is that we be clear about what our National Residue Program test results can tell us about violative residues and what they can't tell us.

The results we obtain from the samples we collect and tests show that the rates of violation are generally infrequent among those sampled. For the specific chemicals and commodities we target, we generally sample at a level that we believe is sufficient to detect with 95 percent confidence a residue violation if it occurs in 1 percent or more of the animal population.

But we do not have the resources, nor do we think it would be a good use of our scarce resources, to test at that level for every one of the thousands of chemical and commodity combinations. Thus, we cannot statistically extrapolate the results we have to the entire spectrum of combinations in the food supply and we cannot make definitive statistically valid statements about all residues.

We have instead a reasonably detailed targeted series of snapshots that give us reasonable confidence that violative residues are not occurring frequently. We can improve the targeting and other elements of our program, but the real solution is to install HACCP systems of preventive controls that don't rely on federally financed testing to detect violations.

I am confident that FSIS is capable of making important changes in its program to protect the public health. I have been impressed with the knowledge, commitment, and motivation of the employees at the agency, and I believe that with a sound regulatory strategy in place, much can be accomplished.

Thank you, Mr. Chairman. I would be happy to answer any questions.

[The prepared statement of Mr. Taylor follows:]

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D C 20250

STATEMENT OF MR. MICHAEL TAYLOR
ADMINISTRATOR
FOOD SAFETY AND INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE

BEFORE THE
SUBCOMMITTEE ON HUMAN RESOURCES
AND
INTERGOVERNMENTAL RELATIONS
OF THE
COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

September 28, 1994

Mr. Chairman and members of the Subcommittee, I am pleased to have this opportunity to appear before you today to discuss USDA's programs to regulate and prevent illegal and unsafe chemical residues and contaminants from entering the Nation's meat and poultry supply. With me today are Dr. Richard Carnevale, Assistant Deputy Administrator for Science and Technology, and Dr. John Prucha, Deputy Administrator for International Programs. Representing the Animal and Plant Health Inspection Service is Dr. Bonnie Buntain, Team Leader, Animal Production (Pre-harvest) Food Safety Project.

The oversight hearings you have held on our Federal food safety programs, backed up by the several studies of the General Accounting Office, have played an important role in documenting the need for change in how Federal regulators approach their food safety responsibilities.

As your efforts have shown, it is time for a basic paradigm shift in food safety regulation. When it comes to chemical contaminants and microbial pathogens, it is no longer sufficient to rely solely on Federal inspectors to detect and correct problems after they occur. We need to move toward risk-based systems of preventive controls under which food manufacturers take responsibility for systematically preventing problems and Federal inspectors are able to verify, and take actions to ensure, that such systems are working effectively.

We plan to propose regulations this fall that will require all meat and poultry plants to adopt the system of preventive controls known as HACCP (Hazard Analysis and Critical Control Points). HACCP is a widely accepted tool that, if implemented properly, will make food safer. It is based on the simple premise that safety must be built into a food product at each step in the process, rather than relying entirely on end product testing to detect and eliminate problems.

HACCP plans must address all potential food safety hazards, including those posed by illegal chemical residues and contaminants. Under HACCP, each plant will adopt appropriate controls to prevent harmful contamination, and FSIS will inspect and conduct tests to ensure those controls are working.

Let me emphasize one important point, Mr. Chairman. HACCP is not a substitute for careful federal oversight of the safety of our Nation's food supply. The public expects vigilance on our part and, in the case of meat and poultry inspection, increased efforts to reduce the risk of foodborne illness associated with microbial pathogens, such as E. coli 0157:H7 and Salmonella. We are making that effort. HACCP will increase our ability to improve the safety of the food supply and protect public health.

I am confident that FSIS is capable of making important changes in its program to protect the public health. I have been impressed with the knowledge, commitment, and motivation of the employees in the Agency. I believe that with a sound regulatory strategy in place, much can be accomplished.

Let me now describe briefly our current program for regulating chemical residues and contaminants.

Residue Control

A key aspect of food safety is the control of residues in food that may result from the use of animal drugs and pesticides, or environmental contaminants. The United States has a complex residue control system, with rigorous processes for approval, sampling, testing, and enforcement.

Three agencies play major roles in protecting the public from residues left in food by drugs, pesticides and other chemicals, and environmental contaminants. The Environmental Protection Agency (EPA) regulates and sets the tolerances for pesticides that can be used in food production and other industrial chemicals that have the potential for contaminating food. The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture is charged under the Federal Meat Inspection Act and the Poultry Products Inspection Act with ensuring that meat and poultry sold in interstate commerce in the U.S. are safe, wholesome, and free of adulterating residues. The Food and Drug Administration (FDA) approves the use of animal drugs and establishes tolerances for those residues in edible tissues. In addition, FDA, in cooperation with the States, investigates drug residue violations referred to the Agency by FSIS and follows up with appropriate enforcement actions. FDA also enforces EPA tolerances for pesticides in food and develops and enforces tolerances and action levels for contaminants in food.

National Residue Program: What It Does

As part of its responsibilities, FSIS has since 1967 conducted the National Residue Program (NRP) to sample meat and poultry for residues. FSIS inspectors collect samples of meat and poultry at slaughtering establishments and from import shipments at the ports of entry. The samples are analyzed for the presence of unacceptable pesticide residues, animal drugs, and other potentially hazardous chemicals that may contaminate meat and poultry.

The goals of the residue program are to assess the occurrence of residues, detect violative residues, and to use the information to protect the consuming public from meat and poultry containing concentrations of residues that exceed the pesticide and other chemical tolerances set by EPA and the animal drug tolerances set by FDA.

The National Residue Program: How It Works

Residue testing of animals slaughtered in the United States is divided into two major activities: population sampling programs and individual enforcement testing. Population sampling programs determine the occurrence and extent of residue violation problems in livestock and poultry. These programs also evaluate the impact of actions taken to reduce violations. During individual enforcement testing, samples are analyzed from individual animals or lots based on clinical signs or herd history. Individual enforcement testing is emphasized in problem populations and is used to prevent residues from entering the food supply. There are three categories of population sampling programs – monitoring, exploratory, and surveillance.

Monitoring involves the sampling of animal populations to obtain a profile of the occurrence of residue violations on an annual, national basis. Information is obtained through a statistically based, random selection of specimens of normal-appearing tissue from inspected and passed carcasses. In addition to profile information, the results are used to identify producers whose animals show violative concentrations of residues. When such producers subsequently offer animals for slaughter, their animals will be subjected to individual testing until compliance is demonstrated. Monitoring programs combined with cooperative prevention efforts with industry have proven effective in reducing the levels of residues found in meat and poultry products. For example, FSIS has historically been concerned about levels of sulfonamides in market hogs. Residue violation rates for market hogs have declined from 6.63 percent of monitoring sample specimens in 1984 to 0.88 percent in 1988.

Exploratory programs study the occurrence of residues for which no residue limits have been established. There are many chemicals, for instance, trace metals, industrial chemicals, and mycotoxins, that may be inadvertently present in animals yet have no

established residue limits. Their presence in edible tissues and the resulting need for residue limits to protect public health have not been established. For example, although not approved for use in the United States, Clenbuterol may be used illegally in some livestock show circles to increase the muscle mass of animals. The FSIS Clenbuterol exploratory project, currently underway as part of the 1994 National Residue Program Plan, is occurring in two phases. The first phase involves sampling from the general populations of heavy calves, heifers, steers, market hogs, sheep, and lambs. The second phase will sample show animals.

Surveillance is used when we know a residue problem exists. Under a surveillance program we examine where residue problems exist, measure the extent of the problem, and evaluate the impact of actions taken to reduce the problem. In surveillance, the carcasses and organs may be retained pending test results. In-plant tests are a key part of NRP surveillance activities. Several tests are used routinely to determine the nature of possible residue problems:

Sulfa-on-Site (SOS): The Sulfa-on-Site, or SOS, test was implemented in 1988 to test swine for sulfonamide residues. SOS is used in the largest swine slaughtering facilities. Laboratory confirmation of violations is required.

Calf Antibiotic and Sulfonamide Test (CAST): The Calf Antibiotic and Sulfonamide Test, or CAST, is used to test bob veal calves – those calves under 150 pounds and less than three weeks old. CAST does not require laboratory confirmation of the result; any violation found with CAST results in immediate condemnation of the calf.

Swab Test on Premises (STOP): The Swab Test on Premises was implemented in 1979 to detect the presence of antibiotic residues in kidney tissue. Laboratory confirmation is required before the animal carcass is condemned.

Fast Antimicrobial Screen Test (FAST): The Fast Antimicrobial Screen Test, or FAST, quickly detects both antibiotic and sulfonamide drug residues in kidneys and livers and has proved to be a suitable replacement for CAST and STOP. FAST was implemented in pilot calf plants in 1993. Extension to all calf plants and cow plants is being planned.

Criteria for Evaluating and Ranking Chemical Compounds

There are several hundred pesticides registered for use in the United States, and as a result, pesticide residues may occur in meat and poultry. The number of potential residues from the use of animal drugs is equally large. In deciding where available resources and testing efforts should be assigned, FSIS must assess relative concerns for those residues most likely to have the greatest impact on public health.

For purposes of developing and managing the National Residue Program, residues are given precedence using a risk assessment procedure, the Compound Evaluation System (CES), developed in 1985 and revised in 1988. The CES has three key elements. First, we determine whether the use of the compound is likely to result in a residue. If so, the second CES factor is inherent hazard or toxicity of the compound. The third is likely exposure.

In determining whether a compound is likely to result in a residue, we are able to rule out compounds that meet the following criteria:

1. There is a zero-day withdrawal period established by FDA or EPA.

2. The compound is biodegraded rapidly to non-toxic products.

3. The compound is not absorbed, or if absorbed, is excreted rapidly.

4. The specific compound and its metabolites are physically unstable in the environment.

The second element, hazard, refers to the toxicity of a compound. A hazard ranking is determined by FSIS toxicologists based on data collected during consultation with EPA and FDA and from scientific literature reporting results of medical and scientific studies, including those on animals and epidemiologic investigations of exposed humans.

The third element is exposure. The most accurate and up-to-date data used to determine the likelihood of exposure to a residue resulting from the consumption of meat and poultry products is compiled from samples collected in FSIS surveys of animals and food products. Excellent data is also available from EPA, FDA, and the reports from the scientific community available in journals. The exposure potential is the risk assessment element most subject to change.

The National Residue Program laboratory testing results are routinely reviewed and the yearly summary is reviewed as soon as data becomes available to update each compound's exposure potential. Indications of changes in exposure potential are: (1) approval for use of a compound is granted or withdrawn by EPA or FDA, and (2) discontinued use of a compound by industry.

The CES ranking, which is a function of the hazard ranking and the exposure ranking, is the basis for determining sampling frequencies in the National Residue Program.

At times information is desirable for compounds where exposure potential may be significant but the compound lacks an official tolerance or other regulatory limit. In those cases the compound may be included in an exploratory phase of the National Residue

Program if suitable methodology is available. If residues are detected from these compounds, FDA or EPA would be notified and a request made for a regulatory limit so that the compound could be included in residue program monitoring.

Imported Product

Federal meat and poultry inspection laws require foreign countries exporting meat and poultry to the United States to impose inspection requirements at least equal to U.S. requirements. FSIS carefully reviews the residue control programs of foreign countries to ensure they can effectively control residues of chemicals and drugs in meat and poultry products destined for the United States. FSIS requires that foreign residue control programs include random sampling of animals at slaughter, use approved sampling and analytical methods, test target tissue for specific compounds, and test for compounds identified as potential contaminants of meat and poultry exported to the United States. In addition, every foreign country eligible to export to the United States must submit annual residue monitoring plans and results of the previous year's testing. These countries then receive an annual certification from the Secretary enabling them to export product to this country.

FSIS' International Programs staff evaluates foreign residue control programs through on-site observation of the foreign country's inspection system. The staff reviews exporting plants, equipment, and laboratories. FSIS inspectors in this country double check the effectiveness of foreign inspection programs by sampling product at U.S. ports-of-entry. Samples are chosen at random from lots selected for reinspection.

The criteria for acceptance or rejection of imported products are the same as those applied to U.S. meat and poultry products prepared under Federal inspection. When test results indicate a violative level of residue in an imported product, every effort is made to locate and destroy any product already in U.S. distribution channels. In addition, subsequent shipments of the same product from the same establishment are retained at port-of-entry until laboratory results are known. If results are negative, product is permitted to move in commerce; if positive, product is refused entry into the United States. In addition, all like shipments from the country are placed on an increased testing schedule until a record of compliance is re-established.

As I mentioned before, foreign countries must meet our residue requirements in order to export meat and poultry product to the United States. If they do not, we will remove them from our list of approved countries, and we have done so in at least five cases. In 1990, Brazil and Israel were delisted because their residue control programs were judged not equal to that of the United States. Germany and Iceland were delisted in 1989 for the same reason. In 1983, Czechoslovakia was delisted because of PCB violations found in product at port of entry.

Preparing the National Residue Program for the Future

The National Residue Program has been very successful in leading the industry to control animal drug and pesticide residues. Nevertheless, we acknowledge that improvements are needed to address current and emerging issues – especially in the context of the transition to HACCP.

HACCP will affect all areas of FSIS, including the National Residue Program. We are beginning to evaluate how the current NRP can be modified to accommodate the adoption of HACCP in slaughter facilities. This will be a multi-agency process involving both FDA and EPA under the framework of a Memorandum of Understanding established in 1984 between USDA, FDA and EPA on cooperation on regulatory issues relative to residues.

As a means of redirecting FSIS activities along the lines of HACCP, the Compound Evaluation System would provide guidance to in the hazard evaluation phase of developing their individual HACCP plans. CES information can provide a useful basis for setting monitoring priorities. Therefore, it is important for the agency to refine this evaluation process to make it most useful to the implementation of a HACCP system. For example, we anticipate focusing more on high priority, hazardous compounds that are the biggest threat to public health. We want to work with producers and plant owners to develop hazard prevention procedures as well as education programs. We believe that industry can, and should, control these hazardous compounds at the pre-harvest stage and during production.

We also plan to improve our port of entry residue testing program as a result of HACCP. We will work with foreign countries – many of whom are already using a hazard control system – to verify HACCP procedures are put into place in foreign countries that are as stringent as those put in place in the United States.

Furthermore, we will continue to target sampling when we are aware of a country having residue problems with a particular compound. As an example, we conducted intensified import testing and initiated other investigations in 1993 when several samples containing chlorfenvinphos - a compound not registered in the U.S. - were found in products coming from Australia and New Zealand.

While current activities will continue under HACCP, we will also reexamine the import residue program to ensure the program best reflects concerns about compounds impacting public health.

Conclusion

In conclusion, we look forward to working with you, Mr. Chairman, and members of this Subcommittee, to implement HACCP and bring about needed changes in our inspection program – including our National Residue Program. HACCP presents a unique opportunity for us to strengthen the entire inspection program by basing it on risk analysis and management principles.

Thank you, Chairman Towns, for inviting me to testify today. I'm happy to answer any questions you or other members of the Subcommittee may have.

Mr. TOWNS. Let me thank you for your excellent testimony.

Up to this point, you have lived up to your billing. I couldn't agree more with your statement. Let me raise a few questions with you.

Listening to your testimony, it seems that you agree with GAO that the current Federal approach to monitoring chemical residues and contaminants in food is flawed.

Mr. TAYLOR. It is flawed in the sense that we currently rely on government testing, sampling and testing of products to determine, and to verify whether residues are violative. And, the current Federal approach is flawed because of the fact that we can never hope to test completely enough to provide the kind of assurance that I think this subcommittee is looking for and that I believe the people, the public, expect.

We need a different paradigm. And we are so much better off—and this is the power of the HACCP paradigm—building in controls to prevent violative residues in the first place rather than relying solely on chasing around to find those violations after they occur.

There has got to be a combination. You don't set up HACCP systems and then not check to verify that they are working properly. There still needs to be sampling. But we can't do a Federal sampling program that all by itself is going to address this issue.

Mr. TOWNS. How can we in Congress help bring about the paradigm shift in food safety regulations that is needed? How can we assist in that?

Mr. TAYLOR. I think as I said in my testimony, Mr. Chairman, the studies that GAO have conducted and the hearings that you held have helped focus the attention and build a case for this paradigm shift.

It is very clear that the agencies are acting on that understanding. FDA has proposed rules for seafood. We will be proposing rules for meat and poultry—HACCP rules—this fall.

I think that we have asked Congress for some things—the pathogen reduction legislation in particular, so that in our statute we can have built into our statutory regime a very clear mandate to target microbial pathogens.

That is the big food safety issue as far as meat and poultry products are concerned. And we certainly want to have the full weight of Congress behind our efforts there.

Mr. TOWNS. You stated that a compound evaluation system can be useful in setting monitoring priority. But GAO found that the system is extremely backlogged. How do you plan to fix the ranking system?

Mr. TAYLOR. Well, I think the appearance of a backlog stems in part from the fact that the list that we are looking at is a very lengthy list. It was not given a lot of scrutiny as it was prepared, so there are a lot of chemicals on that list that arguably shouldn't be among our candidate residues. So we need to do a better job of winnowing out the chemicals that really deserve careful review.

I think that the focus of our efforts needs to be to target on those chemicals that, from a public health standpoint and from the standpoint of the likelihood of violative residues, are of greatest concern and be sure that we have identified those chemicals and have an analysis in place to support the hazard analysis efforts of

companies who we will be asking to establish preventive controls for these very chemicals.

So the focus of our efforts needs to be to look at that list and look at the whole residue program in terms of how it can best support HACCP.

Mr. TOWNS. One question was raised earlier by Congressman Mica, I think. Why doesn't USDA routinely test imported meat for pesticides and animal drugs approved for use in foreign countries but not approved or banned in the United States? With independent testing, how can USDA truly verify foreign country testing results?

Mr. TAYLOR. May I take one moment to explain what we do—to try to protect the American consumer from violative residues in these products and then I will address specifically your question, because the context is important?

We, under our statutes, may allow import of meat and poultry products only after having reviewed a foreign country's system of inspection and found it to be equivalent to ours. And we do that based on reviewing their laws and regulations and also visiting and looking at their inspection program to be sure that it is equivalent to ours.

Eligible foreign programs have to include an approach to chemical residues that is equivalent to our system here for looking at domestic chemical residues. We then conduct what we call a reinspection of that product when it comes into the United States, even though it has been inspected by a foreign authority whose program we have judged to be equivalent. We then reinspect at the port of entry, and we sample about 10 percent of the shipments and do some tests.

We do a certain amount of testing for chemical residues. The number of samples is between 10- and 20,000 a year. We fairly rarely find violative samples. What you are putting your finger on, though, is the question of given the same reality with respect to the international program, that we cannot ever hope to test enough to identify every violative situation, how can we be sure that preventive controls are in place to prevent that violation?

And again, when we move to HACCP, foreign inspection systems in order to be equivalent and to be able to support exports to this country, will have to adopt the same equivalent systems of preventive controls, including with respect to these unapproved pesticides or animal drugs.

And so we will have a far better system in place for preventing the problem. Then the question remains, how much testing should we be doing? How much resource should we be expending in our oversight of that system at that port of entry point?

And I don't think we have a good answer to the question of how much testing is enough. We do limited testing now, because we rely on the foreign systems. I think as we move toward HACCP, we are going to have to answer this question generically, not just for unapproved pesticides or animal drugs. We are going to answer the question generically: How much testing of HACCP systems is appropriate? And that is going to require a discussion that involves not just the agencies but the public and I think the Congress because there is a resource issue there as well.

Mr. TOWNS. Thank you very much.

At this time I yield to Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

Mr. Chairman, a couple of things. One of the controversies that has come to the attention of this subcommittee is a controversy involving the meat industry in general and in particular an allegation by the red meat industry that it is subject to a stricter standard of health and safety with respect to such issues as fecal contamination than the poultry industry is subject to.

What I would like to know is, have you had enough time in your present position for that to have come to your attention to the extent that you can evaluate it and respond to that?

Mr. TAYLOR. I certainly can respond in general terms. These two programs developed and their basic elements were put in place at different times. The poultry program being relatively new came up in the 1960's. The meat inspection program dates back to the beginning of this century. And out of those differing historical origins, documented by a study done a couple of years ago by an outside group the department contracted with, there are a number of differences in the regulatory schemes and requirements.

And one example Secretary Espy encountered when he came in was that a zero tolerance for fecal contamination of red meat on the books was not being enforced aggressively, but there was no similar zero tolerance for fecal contamination on poultry. He has proposed to establish that zero tolerance for poultry.

What I think I have been focusing on is the future and how we can be sure that both of these product categories, both red meat and poultry, are subject to an appropriate set of public health-driven food safety standards, focusing on microbial pathogens and making sure that we have adequate sets of preventive controls in place.

Both regimes will be obviously subject to the HACCP requirement. And we are considering approaches to microbial testing that would apply to both red meat and poultry. So even though there has been this difference that comes from different historical origins, I think you are going to see a lot of convergence as we bring the science of microbiology into the program and set a floor and set expectations for the industry.

Mr. SCHIFF. One other question. As I am sure you heard in the testimony already today, there is a great deal of discussion of centering all government food safety responsibilities in a single agency, and that single agency may well be over on the health side of the government organization rather than on the Department of Agriculture side.

I wonder, if—I know you are head of an agency now that, of course, deals with this issue, but I want to assure you that this is being approached from an administrative point of view and not through any indictment of your agency or of you or the people that you work with.

With that in mind, do you have an opinion as to whether the consolidation of all Federal food service inspection would be best in one agency, and if so, what agency would that be?

Mr. TAYLOR. I will give you my thoughts about that. If we were starting from scratch today to design a Federal food regulatory program, I don't think any of us would design it the way it exists

today organizationally because as this committee has documented and GAO has found, we do have a system where jurisdiction is divided, there is a lack of consistency in the statutory regimes. It is not an ideal system. And I think it is a very fair question for the Congress to be asking.

The system is a creature of the statutory framework that has evolved, again historically over a period of years to get it where we are today. And I think given the public interest in the food safety issue it is a fair question to be asking.

I have a very specific job to do at the Food Safety and Inspection Service, which is consuming 110 percent of my attention, which is to bring the science of microbiology into our program and to deal with the very immediate issue of how we can reduce the risk of foodborne illness from microbial pathogens. That is the focus, regardless of the discussion of organizational change, that is the focus of this program, and my focus at FSIS.

This is a question ultimately that I think will be answered by the Congress. And it is certainly a fair question to be asking.

Mr. SCHIFF. Thank you, Mr. Taylor. I yield back.

Mr. TOWNS. I yield to Congressman Mica.

Mr. MICA. Welcome, Mr. Taylor. I know you are the new kid on the block.

Mr. TAYLOR. That only goes so far, Mr. Mica.

Mr. MICA. I think if you asked some of your colleagues who have been before me from your agency, I do allow a grace period, though.

Mr. TAYLOR. Thank you.

Mr. MICA. But one of the great things about serving here and just being here now 20 months is you develop an institutional memory. And these people come back. I always say God brings them back to me so I get another shot at finding out if they have followed through on what they said they were going to do. But you have got quite a challenge, and again I look forward to working with you.

There are a couple of things that I wanted to talk about today. First in these GAO recommendations, it says they have identified five areas of weakness. I want to talk about a couple of them.

One is that chemicals posing similar risks may be regulated differently under different laws. And then we got into another problem, it says the MPR's basic flaw is the choice of chemicals tested and the methodology used to choose samples for testing.

In addition, the program suffers from limited support from EPA and FDA to identify potentially hazardous chemicals and to prosecute violations.

How are we doing with my good friends at EPA as far as cooperating?

Mr. TAYLOR. Well, I think there is a good record of cooperation.

Mr. MICA. That is not what this says.

Mr. TAYLOR. Well——

Mr. MICA. The date on this is September 28, 1994.

Mr. TAYLOR. There is a lot of collaboration and coordination that goes on.

Mr. MICA. Is there hope?

Mr. TAYLOR. There is room for improvement in that.

Mr. MICA. Is EPA working with you now?

Another thing, too, is that FSIS cannot ensure that the compounds presenting the greatest risk have been identified and are being tested under the program. This occurs, one, because FSIS has ranked—in other words, prioritized—only about a third of the 367 compounds it has identified as being of potential concern for meat and poultry. And, two, methods have not been developed for all compounds.

Furthermore, only 24 of the 56 compounds tested in 1992 were of high priority.

So it looks like what we are doing now isn't really addressing the greatest risk or addressing the greatest priority items. Is that correct?

Mr. TAYLOR. I agree there is room for improvement in how we target those chemicals that pose the greatest concern with respect to violative residues and public health concerns.

Mr. MICA. Now, when will we have before us some proposals, specifically legislative proposals, to correct what we have been talking about here today?

Mr. TAYLOR. On the specific issue, Mr. Mica, of focusing better on chemicals of greatest concern, I don't think the solution is necessarily legislative. We think that——

Mr. MICA. Well, are we going to do this, one, two, three, and with what deadlines? Can you give me some estimate?

Mr. TAYLOR. The major step forward toward addressing this will be our proposal this fall to require that all facilities have HACCP plans.

Mr. MICA. And when will we expect that? By Thanksgiving? Giftwrapped for Christmas?

Mr. TAYLOR. I said fall. That is our goal, to publish it this fall.

Mr. MICA. Well, fall just started the 23rd, so we will say by the beginning of——

Mr. TAYLOR. The day before the beginning of winter is my goal.

Mr. TOWNS. Are you saying Thanksgiving because of turkeys?

Mr. MICA. We won't get into turkey and poultry inspection reports, but in any event, I am trying to say when specifically. We are looking for some things there.

Now, I hate to jump but I only get so much time and the light goes off in a hurry. But let me ask you, too, one of the other problems identified here clearly is that there is a very high number of violations, very few of these violations are investigated, an even smaller number of regulatory actions, and I guess one prosecution.

It says one of the problems is that agencies lack strong enforcement authorities to adequately deter or penalize violators. Do you need more legislative authority?

Mr. TAYLOR. Absolutely.

Mr. MICA. When will you have your recommendation to us?

Mr. TAYLOR. The Department of Agriculture has a bill pending that would give us, with respect to our enforcement duties—I think you are referring in part to the role that FDA plays in the enforcement area—but would give us authority, for example, to impose civil penalties, particularly on these repeat violators.

There is no question about the fact that in addition to having preventive controls in place that responsible companies would implement to prevent violations, we do need remedies for that un-

usual case where you have a repeat violator and people responsible for large numbers of violations. We do need civil penalty authority.

Mr. MICA. So you have a proposal that is ready to go?

Mr. TAYLOR. There is civil penalty authority in the Pathogen Reduction Act that we have advanced. And that would certainly address the part of the enforcement spectrum that USDA addresses.

Mr. MICA. Well, we will work with you.

Mr. TAYLOR. Please.

Mr. MICA. These hearings are fine, but if we don't do something to address the problem—let me make another point before I conclude.

My intent here is not to bash industry. My intent is to have you work with industry, because I think you could put 1 million inspectors out there and never accomplish the elimination of all of the risks. That is not going to work. So working with them is our intent. But where you have real violations and repeated violators or violations from one source and nothing is being done about it——

Mr. TAYLOR. That disserves the companies who are complying.

Mr. MICA. Exactly. And so that is part of our intent. And we will work with you on that, and if it is other committees of jurisdiction, we need to see that this is moving forward.

I think my time has run out. I wanted to get into some other issues.

Mr. TOWNS. The gentleman is right. His time has expired.

Congressman Portman.

Mr. PORTMAN. Thank you, Mr. Chairman.

Mr. TOWNS. Let me say to the gentleman, if he would like to submit additional questions for the record, please feel free to do so. I will leave the record open for 10 days.

Mr. MICA. Thank you.

Mr. PORTMAN. As the new kid on the block, you are correct, the honeymoon is short, not just with my colleagues.

First on the restructuring questions, Mr. Schiff asked you the question that I had posed earlier to the GAO representatives. I continue to be confused as to the administration's position on restructuring.

I think it is something appropriate for the Congress to consider. And now what I think is a strong recommendation from GAO—NPR suggested that FDA was the right place in which these food safety responsibilities would be placed. And GAO seems to be saying that an independent entity, new department or agency would be appropriate. But it should be health based.

Mr. Schiff asked you what your opinion was and after talking about your immediate concerns and the need to bring microbial scientific expertise to the department and focus on HACCP, you essentially said you had no opinion, I think. Is your opinion no opinion?

And second, do you think that it is fair to say that the administration does not have a position on this issue?

Mr. TAYLOR. As far as I know, and I stand to be corrected, the administration has not taken a formal position on any of the bills that have been introduced. You are familiar with the analysis and the recommendation contained in the National Performance Review.

I don't know what the correct ultimate answer is or whether there is a single correct ultimate answer. I do think there are some considerations that need to be taken into account as Congress considers this question.

One obviously, the food safety agency or agencies, if there were to be several food safety agencies under the current regime, need to have clear statutory mandates to put public health first, to put food safety and the protection of the public that consumes these products first.

The thrust of our pathogen reduction legislation is to build into our statutory charge a command to which we can be held accountable that we seriously address microbial pathogens using the best science available to reduce the occurrence of foodborne illness.

You also need resources. And I think before, frankly, we can decide what the right answer is on this organizational question, Congress and the public have to come to grips with the resource question.

I personally don't believe that the problem that we have at the Federal Government is too much resource applied to food safety. There are a lot of issues concerning whether we are making the optimal use of that resource and our shift to the HACCP paradigm at both FDA and FSIS reflects the recognition that we need to move to a paradigm that makes better use of existing resource.

But there are elements of the chain of food production and processing and distribution that aren't really addressed all by the Federal regulatory system. Transportation, for example. We put intensive effort into what happens in meat and poultry processing plant. Do we really have adequate oversight about what happens when that product goes on thousands of trucks? We don't want an inspector on every truck, because that's not the best use of resources but should there be some oversight of that?

How do we deal with the retail level? Historically and currently, the Federal Government sets standards and provides technical guidance to the States and FDA has the lead on that and we rely on States to inspect restaurants and enforce cooking temperatures for ground beef, for example. What should be the Federal role in overseeing that if it should be different than it is today?

And the import situation I think is one of the biggest questions. It is easy to raise questions about imported product. Do we have the right level of inspectional oversight there? I don't think that the answer to the food safety rests in some organizational fix.

There are some very basic issues that need to be addressed in deciding how we want to do food safety at the Federal level. And I think if we get into addressing those, then perhaps an organizational solution flows from that. But to think that simply moving pieces around on the organizational chart will solve the problem, I think would be a mistake.

Mr. PORTMAN. My reaction would be twofold. One, I think it is not logical to assume that the first step is to get a sense from the public as to the cost. I think the first step is for the experts, which is you and the FDA and GAO and others, to tell us what those costs would be, given certain parameters.

Second, those issues which you rightly suggested need to be resolved are issues that need to be resolved whether we go to one

agency or not. I think the overwhelming evidence is that there is currently inefficiency in the system. There are currently some potential conflicts of interest in the system. And there is currently some duplication of effort. And all those issues you addressed do need to be looked at by Congress. But I don't think they should stand in the way of the reorganization.

So I hope the administration to summarize, would have a position on the issue, would come up with a position. I assume it would be consistent with the National Performance Review which got a lot of press and publicity at the time but if it is not the administration's position, they would tell us otherwise.

Two quick questions. First, with regard to the imports coming in from other countries, I was misinformed. I thought that you didn't test for all chemicals or chemical compounds that are illegal in this country.

Mr. TAYLOR. We don't test for all of them. We do a certain amount of testing at that reinspection point when meat and poultry is offered for import, but we don't test for all unapproved chemicals here.

We do rely on and see that the foreign system has a mechanism for assuring that product destined for the United States, from, say, Australia, is complying with our laws. But that is what we rely on.

Mr. PORTMAN. Are you saying that the Australian authorities test for the chemicals and compounds that are illegal in this country whether they are illegal or not in Australia?

Mr. TAYLOR. They are responsible and we review their programs to see how well they are carrying on. They are responsible for assuring that product coming out of a plant that is approved for export to the United States is meeting our U.S. regulatory requirements.

Mr. PORTMAN. I am interested in that. I wonder why then we aren't testing here on our shores for those same chemicals and chemical compounds.

Mr. TAYLOR. The issue in those countries I am sure is the same here. How much testing is enough? And is testing really the answer?

We think that the core of the answer is not more testing but HACCP. A lesser or perhaps today's level of testing might be adequate to verify HACCP, but we have got to get HACCP in place.

Mr. PORTMAN. Let's talk about HACCP for a second and then I will defer to the chairman.

I agree with you that HACCP seems to make sense. If we are going to test for anything, I don't know why we don't test for the chemicals that we are asking other countries to test for.

On HACCP what we are grappling with is what is the appropriate legislative role. You talked earlier about some statutory guidelines that might be necessary immediately for USDA to carry out its microbial pathogen program. You look at the GAO report on page 41. It lists matters for congressional consideration and suggests that we require you, FSIS, to establish risk-based HACCP systems and so on in industry.

Do you need this? It seems that you are going ahead with a fairly aggressive HACCP program. Are you looking for statutory guidance or affirmation of your programs?

Mr. TAYLOR. We have not asked for statutory direction to do HACCP. We believe we have the legal authority to do that under our current statutes.

We also believe we have authority to address the microbial pathogen problem under our current law. We believe in that particular area it would be very desirable to have the weight of Congress behind what are some very major changes in how we are going to do business in meat and poultry plants.

If Congress wanted to put its weight behind the HACCP initiative, I certainly have no objection to that either. But we feel we have very sufficient legal authority to do it and we are proceeding this fall on that basis.

Mr. PORTMAN. Thank you.

Thank you very much.

Mr. TOWNS. Thank you.

Let me thank you, Mr. Taylor, and your staff for your testimony, and I invite to you participate in the next panel to answer questions from the Members regarding the larger issues of the Federal Government's system to monitor chemical residues and contaminants in food.

I understand that you are testifying before another committee so you are excused to leave when you must. So stay as long as you can.

Mr. TAYLOR. I will stay as long as I can. Thank you.

Mr. TOWNS. At this time, let me ask Dr. Fred Shank, Director of the Center for Food Safety and Applied Nutrition of the FDA, to come forward; Dr. Steven Sundlof, Director of the Center for Veterinary Medicine, FDA; and Dr. Lynn Goldman, Assistant Administrator for Prevention, Pesticides and Toxic Substances, of the EPA.

[Witnesses sworn.]

Mr. TOWNS. Please let the record reflect that they answered in the affirmative.

I assume you have no other persons answering. If so, they will need to be sworn in. Your name?

Mr. JONES. John Jones, FDA.

Mr. MITCHELL. I am Burt Mitchell.

[Witnesses sworn.]

Mr. TOWNS. Why don't we begin with you Dr. Shank. You know that you have 5 minutes to summarize your statement and your entire statement will be included in the record.

STATEMENT OF FRED R. SHANK, Ph.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY STEPHEN SUNDLOF, D.V.M., Ph.D., DIRECTOR, CENTER FOR VETERINARY MEDICINE; AND BERT MITCHELL, DIRECTOR, OFFICE OF SURVEILLANCE AND COMPLIANCE

Dr. SHANK. Yes, sir. Good morning, Mr. Chairman and subcommittee members.

Also representing FDA with me is Dr. Stephen Sundlof, the Director of the Center for Veterinary Medicine. We appreciate the opportunity to participate in this hearing and present FDA's views on the regulation of chemical residues in the food supply.

As you are aware, the U.S. food supply is one of the safest and most abundant in the world. FDA is committed to ensuring that safety and to protecting the American consumer from unsafe, adulterated, or misbranded food.

The agency strives constantly to improve its existing monitoring programs and enforcement efforts. But we are concerned that we may be unable to sustain the pesticide and contaminants monitoring program we have in place. To this end, we welcome your ongoing interest in this subject.

I will briefly describe some of the programs within the Center for the Food Safety and Applied Nutrition.

The National Drug Residue Milk Monitoring Program is one of several agency programs to monitor milk for drug residues. Data from this program allows FDA, the States and the dairy industry to assure the public that animal drugs are used in compliance with laws and regulations; violations, when detected, can be traced back to the offending producer, and enforcement activities can be undertaken.

In January of this year, the milk program was updated to add analyses performed by certified State laboratories using what we call quick screening test kits that were provided by FDA. The updated program results in many more samples being analyzed than was possible before these kits were available, and during the first half of 1994, 2,500 tests were conducted by States with no violative samples found.

The national milk drug residue data base is a new effort designed to track the amount and types of drug residues in milk. This data base includes all of industry and State information from their respective programs. At this time, 48 States and Puerto Rico submit data. The data base currently contains results of over 3.25 million drug residue samples. Of this number, less than one-tenth of 1 percent of the tankers of milk tested positive for any drug residue.

EPA, USDA, and FDA share responsibilities for the Federal regulation of pesticides used on food or feed. Our role is monitoring. Over the past 5 years, FDA has sampled and analyzed over 75,000 separate domestic and import food shipments for a wide variety of pesticide residues. Between 1 and 2 percent of the domestic samples and 2 to 5 percent of the import samples were violative. Of the violative samples, none were deemed to represent a safety hazard. We firmly believe that the pesticide residues in the U.S. food supply present very low risk to public health.

Finally, we are working closely with EPA and USDA in the development of the new pesticide legislation. This legislation will more effectively regulate pesticides and low levels of carcinogens from pesticides in the food supply, as well as to provide for more effective monitoring.

Under the Total Diet Program estimated dietary intakes are determined from various substances, including pesticides, toxic metals and chemical contaminants.

The study has shown a dramatic decrease in the exposure to persistent pesticides that have been banned by EPA such as chlordane, heptachlor and DDT. It has also shown consistently that the levels of pesticides in the U.S. diets do not present a health

risk to Americans. The dietary intake levels of chemicals such as lead have declined markedly since the 1970's.

And finally, I want to reiterate a statement that I made to this committee in May. FDA believes that it is time to consider improvements in the existing food safety regulatory system and to move forward with the hazard analysis and critical control points [HACCP] approach to food safety. Control of chemical contaminants and drug and pesticide residues will be a part of HACCP.

In January of this year, FDA proposed a preventive system for seafood processors in accordance with HACCP principles. We have since taken two additional steps.

In August, FDA issued an advanced notice of proposed rulemaking asking for public comment about whether and how the agency should extend the HACCP principles to all foods. FDA also invited volunteers from the food industry to participate in a pilot study to develop and implement programs based on HACCP principles. The purpose of this pilot program is to obtain firsthand information for FDA to use in implementing this program. We are also working very closely with the USDA in developing the policies based on HACCP that will result in a uniform and consistent system for all foods.

We appreciate the fact that GAO recognizes the importance of HACCP programs on the continued safety of our food supply.

Thank you for the opportunity provided us to participate in this hearing. Thank you, Mr. Chairman.

[The prepared statement of Dr. Shank follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

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AND

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U.S. FOOD AND DRUG ADMINISTRATION
PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS
COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 1994

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman and Members of the Subcommitee:

I am Dr. Fred Shank, Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration (FDA). Also representing FDA with me today is Dr. Stephen Sundlof, Director of the Center for Veterinary Medicine (CVM). We appreciate the opportunity to participate in this hearing and present FDA's views regarding the regulation of chemical residues in the food supply. Our statement will describe FDA's current responsibilities with respect to animal drug residues, pesticides, lead and other heavy metals, and chemical contaminants in our food supply.

INTRODUCTION

As you are aware, the United States food supply is one of the safest and most abundant in the world. FDA is committed to ensuring that safety, and to protecting the American consumer from unsafe, adulterated, or misbranded food. The agency strives constantly to improve its existing monitoring programs and enforcement efforts. To this end, we welcome your ongoing interest in this subject.

In your letter of invitation, you asked to what extent does FDA regulate and prevent illegal, unacceptable and/or unsafe chemical residues and contaminants in the Nation's food supply. The Federal Food, Drug, and Cosmetic Act (FDC Act) charges FDA with the responsibility to ensure that food in the marketplace is safe and wholesome, and truthfully and accurately labeled. FDA carries out these responsibilities by: inspecting firms; sampling and analyzing products to determine if the producers of these goods have complied with the provisions of the FDC Act; and taking appropriate enforcement actions when the agency finds that firms are not complying with the law. But, having said that, the law places the burden of ensuring that animal drugs are used safely and appropriately, that registered pesticides are applied properly according to label directions, and that contaminants are controlled as much as possible in the production of food through Good Manufacturing Practices (GMPs), on food manufacturers, producers, and distributors.

Through FDA's premarket approval activities for new animal drugs and for food and feed additives, and through informal and formal enforcement actions, the agency can minimize unsafe and illegal chemical residues and contaminants in the food supply. Some residues, however, may be unavoidable due to environmental contamination or other activities of man. In these instances, FDA's job is to determine the levels of a particular contaminant that may pose a health hazard to various segments of the population and take any necessary steps to protect consumers from exposure to these contaminants.

As FDA has testified previously before this Subcommittee, when public health issues are being ranked by food safety experts,

chemical issues generally are given a lower level of concern than microbiological hazards. This is not to suggest that we view chemical residues in foods lightly. In fact, based on the definition of monitoring used by GAO in its study and for the purposes of this hearing, in Fiscal Year (FY) 1993, FDA expended approximately 25% of the annual budget for food safety activities on programs related to monitoring the food supply for chemical residues.

While microbiological hazards produce an immediate, acute effect, sometimes involving many people in a single episode, with reactions ranging from gastrointestinal upset to death, chemical hazards may take a lifetime to manifest themselves as disease, or may even show a delayed effect as genetic changes in the next generation. FDA cannot and will not ignore either type of hazard. Pathogenic microorganisms, naturally occurring toxicants, chemical contaminants, and improper food production and handling practices all have the potential, individually or in combination, to be a source of illness. FDA's story with respect to chemical residues and contaminants is generally positive: the food producers and other industries involved have worked with FDA to reduce exposure to contaminants.

Before we describe specific activities in each of the areas outlined in your letter, we would like to describe a particular program, FDA's Total Diet Study, which we believe is one of the best available, overall indicators of the levels of pesticides, heavy metals, and industrial contaminants to which Americans actually are exposed.

The Total Diet Study

Under this program, market baskets of foods are collected four times per year, once from each of four geographical regions of the U.S. Each market basket consists of over 250 foods purchased from local supermarkets in three cities in a geographical area. The foods, chosen on the basis of dietary intake data to represent the diet of the U.S. population, are prepared as would be done in the home, and then analyzed. The levels of the various substances found, along with food consumption data, are used to estimate the dietary intakes of these substances for fourteen selected age/gender groups, ranging from infants to senior citizens. Initiated by FDA in 1961, the program has been expanded to include dietary intake estimates of essential minerals, pesticide residues, toxic metals, and industrial chemicals.

The Total Diet Study has shown that the dietary intake levels of chemicals such as lead have declined markedly since the 1970's. For example, according to data from the 1982 Total Diet Study, the average lead intake for children weighing 9 kilograms (kg) (6-11 months old) was 15.5 micrograms per day; for children weighing 13 kg (2 years old) the average daily lead intake was

25.2 micrograms. The Total Diet Study data reveal that by 1991 the average lead intake had dropped for these two groups to 1.8 micrograms and 1.9 micrograms per day, respectively. Thus, data from the Total Diet Study indicate that from 1982 to the present, dietary lead intake has declined markedly. We believe this is due to reduction of lead solder in food cans (in which FDA played a major role) and conversion to unleaded gasoline.

In addition, the Total Diet Study has shown consistently that the levels of pesticides in U.S. diets do not present a significant health risk to Americans. These levels are well below both the reference doses established by EPA and the acceptable daily intake (ADI) levels set by the World Health Organization and Food and Agricultural Organization. Finally, the Total Diet Study has shown, overall, a dramatic decrease in the amount of dietary exposure to environmentally persistent pesticides banned by EPA, such as heptachlor, chlordane, dieldrin, and DDT.

FDA will submit for the record a summary report on the Total Diet Study which describes the findings of this program in greater detail.

Mr. Chairman, your letter of invitation also raised the question of whether there are obstacles or limitations that impair FDA's efforts to regulate chemical residues and, also, whether there are alternative approaches that may address any vulnerabilities in the Nation's food supply. Contrary to GAO's statements that FDA's monitoring activities are ineffective, the results of the Total Diet Study indicate that the food industry and FDA's food safety assurance programs are generally functioning effectively. Yet, the agency currently faces new stresses and challenges. New food processing and packaging technologies, new food distribution and consumption patterns, increasing public health concerns about low levels of certain chemical contaminants, and new microbial pathogens all contribute to today's food safety challenge. The size, diversity, and international character of the food industry add to the stress on FDA's food safety assurance program as well, with FDA's current inventory listing over 30,000 food manufacturers and processors. The number of foreign manufacturers and processors shipping food products to the United States is continuing to increase. In 1992 alone (the most recent year for which we have data), there were well over 1 million food import entries. Given current constraints on government resources, it is unlikely that FDA will ever have sufficient resources to inspect, sample, and analyze more than a small percentage of all food products, domestic as well as imported. FDA's goal is to use its resources in the most effective way to minimize consumer exposure to unsafe products.

FDA's current regulatory strategy, with its emphasis on periodic visual inspection of food facilities and end-product testing, was designed to control the problems that were known to exist when

the FDC Act was enacted in 1938. FDA's inspections can determine the adequacy of conditions in a food plant at the time of the inspection, but not whether the company has in place a food safety assurance system that is operating reliably and consistently to produce safe food at all times. Furthermore, FDA's current system is generally reactive. It is effective in detecting and correcting problems after they occur, but except in certain limited areas such as the regulation of low-acid canned foods, it is not currently based on a system of preventive controls.

For all these reasons, FDA determined that it was time to consider improvements in the agency's program. In January 1994, FDA proposed a preventive system for seafood processors, in accordance with Hazard Analysis and Critical Control Point (HACCP) principles. HACCP is a preventive system of hazard control in which the food producer, processor, and manufacturer identifies the critical processing points, establishes a system for monitoring those points, and keeps records of that monitoring. The producer takes corrective actions when control at a critical processing point is lost, including proper disposition of the food produced during that period, and documents the action taken. This system is not new; FDA has required this type of program for low-acid canned foods since the 1970's.

In August 1994, FDA issued an Advance Notice of Proposed Rulemaking, asking for public comment about whether and how the agency should extend HACCP principles to all foods, and in a separate notice, FDA invited volunteers from the food manufacturing industry to participate in a pilot study to develop and implement programs based on HACCP principles. The purpose of the pilot program is to obtain information that FDA can use in deciding whether to develop and implement a regulation to require food manufacturers, both domestic and foreign, to operate based on a HACCP system.

The implementation of HACCP would achieve the agency's important public health goals by making the food supply safer through prevention of food safety problems, including the types of problems we are discussing today. It would also enable Federal, state, and local officials to make more efficient use of existing resources devoted to food safety. This would also improve the ability of the Federal government to provide consumers with the assurance that the U.S. food supply is safe.

I will now describe FDA's programs with respect to each of the chemical residues that you have identified: animal drugs, pesticides, lead and other heavy metals, and environmental contaminants, such as dioxin.

ANIMAL DRUG RESIDUES

In the United States, the protection of the public from unsafe residues of veterinary drugs is a shared responsibility between USDA's Food Safety and Inspection Service (FSIS), EPA, and FDA. The FSIS operates the National Residue Program, a testing program to help prevent the marketing of animals containing illegal residues of pesticides, drugs, and chemical contaminants. Although a substantial portion of FDA's work is focused on preapproval, compliance with good manufacturing practices, and detection of illegal distribution and use of veterinary drugs, the agency places a high priority on identification of potential exposure to drugs, and agricultural or industrial chemicals, and prompt preventive, regulatory, or recall measures to protect the public health.

FDA's Role in Setting Animal Drug Tolerances and Withdrawal Times

The use of drugs to control and treat animal disease and to promote faster, more efficient growth of livestock is a common practice. FDA requires animal drug manufacturers to show that each new animal drug [including those intended for use in animal feeds (medicated feeds)] is safe and effective for its intended use before it is approved for marketing. To ensure the safety of animal-derived foods, the agency carefully reviews the safety of the drug for both the animal and humans who consume tissues from the treated animals, and, if necessary, sets a tolerance for the drug, which includes a safety factor to prevent harmful effects on consumers of such foods. The Agency first determines the level at which the drug does not produce any measurable effect in several types laboratory animal studies. From this, the Agency determines an acceptable daily intake (ADI). A drug residue tolerance and withdrawal time are then determined so that the concentration of drug residues in edible tissues are below the ADI. The withdrawal time is the period of time during which the animals are not administered the drug to ensure that residues in excess of the tolerance are not present in the food. For drugs approved for use in food-producing animals, additional safety factors are included in the calculations used to set the ADI and tolerances.

Toxicology, residue, and metabolism studies are also required. If the product will cause residues in tissue, manufacturers also must submit a reliable assay method for detecting drug residues in edible tissues of slaughtered animals and in milk. These analytical methods are reviewed by FDA and FSIS before the drug is approved to determine suitability of these methods for enforcement purposes.

An estimated 80 percent of U.S. livestock and poultry are treated with some animal drugs during their lifetime. The proper use of approved drugs in the production of food-producing animals has

benefitted the consuming public by increasing production at reduced cost and improving the quality of these food items. When approved drugs are administered to animals according to label directions, unsafe residues should not occur.

Improper use of animal drugs is the most frequently found cause of residues in edible animal products such as meat, milk, or eggs. To protect the public from such residues in meat and poultry, FDA cooperates with FSIS in a program to monitor the use of these animals drugs, identify improper use and take action to prevent future illegal use by a producer. FDA is responsible for monitoring drug residues in milk, eggs, fish, and honey.

Illegal Residues in Meat and Poultry

When FSIS finds veterinary drug residues in edible animal tissues above the tolerance set by FDA, it notifies FDA so that a follow-up investigation may be undertaken. FDA evaluates all reports of residue violations and initiates on-farm investigation of the most violative situations. An investigation includes visiting the farm or feedlot from which the animal was shipped to slaughter and interviewing the producer and veterinarian involved. The purpose of the investigation is to determine the cause of the residue and to identify the responsible individuals. FDA then seeks voluntary compliance from the responsible individuals and encourages good husbandry practices to prevent future residue violations. If compliance is not forthcoming, regulatory action is considered. FDA focuses its regulatory and enforcement activities (i.e., warning letters, injunctions, prosecutions) on individuals with a history of continuing illegal residue violations, especially those individuals for whom USDA/FSIS has reported two or more violative samples in a twelve month period. FDA, by itself, cannot investigate all of the initial residue violations reported to it by FSIS. FDA has therefore negotiated contracts and other agreements with 28 state regulatory agencies as part of an overall FDA Tissue Residue Reduction Program.

In past years, the most common causes of residue violations have been the failure to adhere to the withdrawal times set by the agency. Other common causes included cross contamination carryover in feed milling operations (usually those located on the farm), failure to keep proper animal identification and treament records, poor husbandry practices, and extra label use or exceeding recommended dose for animal drugs. Of those incidents where responsibility for the violation could be assigned, the majority were due to producers, family members, or employees. Veterinarians were responsible for a small percentage of the cases.

Because data have shown that producers bear primary responsibility for causing the majority of violative residues,

CVM has issued a Compliance Policy Guide (CPG) entitled "Proper Drug Use and Residue Avoidance by Non-Veterinarians" to outline some of the principles that we believe are key in a quality assurance program on the farm. In this CPG, FDA recommends that persons involved in food animal production establish systems to ensure that animal drugs are used properly and to prevent potentially hazardous drug residues in edible animal products. These recommended control points include: a method to identify and track animals to which drugs were administered; maintenance of medication/treatment records; proper storage, labeling and accounting of drug products and medicated feeds; and the education of all employees involved in treating animals on proper drug use, including observance of drug withdrawal times. Establishing and maintaining such systems should help producers comply with the law and prevent the marketing of meat, poultry, and other animal products that contain illegal drug residues. Under a HACCP system, animal identification and proper adherence to withdrawal times would be critical control points.

Drug Residue Avoidance Programs - Milk

FDA's Grade A cooperative program with the states, National Drug Residue Milk Monitoring Program (NDRMMP), and National Milk Drug Residue Database are the safety net for ensuring that American dairy products do not contain harmful residues of animal drugs.

FDA/State Cooperative Programs

The cooperative relationship between FDA and the National Conference on Interstate Milk Shipments (NCIMS) provide an effective structure for regulating milk. The Pasteurized Milk Ordinance (PMO) is NCIMS' working document that establishes minimum standards for the protection of Grade A milk in the U.S.

The cooperative relationship between FDA and NCIMS has three facets. First, state inspectors from each state's regulatory authority visit each Grade A dairy farm semiannually and milk processing plants on quarterly basis. Inspectors observe the drugs present on the farm to determine if they are properly stored and labeled. At the milk processing plant, they review records of drug residue testing. Two successive violations during consecutive inspections result in initiation of procedures to suspend a Grade A permit. Additionally, the PMO requires that each dairy farm's raw milk be tested for beta lactam drugs four times in each six month period. This supplements the requirement that industry test for beta lactam in each bulk milk tanker before it is processed. Positive results from these tests result in traceback to and regulatory action against the milk and farm involved.

Second, State Rating Officers perform audit inspections by visiting a representative number of farms and milk processing

plants, and scoring them for sanitation and drug violations. This is done at least once every two years.

Finally, FDA field staff inspects farms and milk plants, and evaluates the state regulatory agency to ensure they meet the standard established in the PMO. Generally, this is performed at least once in each three year period. FDA also sponsors extensive training courses for veterinarians, extension personnel, state regulatory officials, and industry representatives to help protect the Nation's milk supply from residues.

National Drug Residue Milk Monitoring Program (NDRMMP)

The NDRMMP is a joint program involving FDA, all fifty States and Puerto Rico. The program is designed to provide an indication of animal drug residues that may be present in milk and, by implication, provide insight into the extent to which farmers, drug distributors, and veterinarians comply with Federal regulations concerning administration of such drugs to dairy cattle.

Milk samples for FDA monitoring purposes are collected mainly by State inspectors from tanker trucks at randomly selected sites. These samples are analyzed by FDA's Denver laboratory using the latest analytical methodology. From February 1991 to January 1994, over a thousand samples of milk were analyzed for 8 sulfonamides, 3 tetracyclines, chloramphenicol and beta-lactam antibiotics. Only one of the samples analyzed during this period was confirmed to contain a violative residue.

In January 1994, the milk program was updated to add analyses performed by certified State laboratories using "quick screening" test kits that were provided by FDA. The updated program results in many more samples being analyzed than was possible before the kits were available. In the first half of 1994, states reported running a total of 2520 tests for beta lactam drugs, chloramphenicol, sulfonamides, tetracycline, and gentamicin.

None of the 2520 samples contained violative residues following confirmatory analyses. However, some results of residues above the level of detection, but below the tolerance or "safe levels" were detected. Findings of residues at these levels indicate that the adulterant may have been diluted. The States are asked to conduct tracebacks and institute enforcement action against the producer who contributed the residue-containing milk.

The transfer of technology to the States is an additional benefit of this program, because it greatly increases assurance that the milk supply is safe.

National Milk Drug Residue Database

The national milk drug residue database is designed to track the amount and types of drug residue testing performed on milk and to provide data on the incidence of positive samples. The database will also provide information on trends for use in educational and analytical initiatives.

The database contains information on drug family, method of analysis, number of screening tests, number positive, and the disposition of the positive milk. This information also includes all the industry and State information for their respective testing programs. At this time, 48 States and Puerto Rico submit data to the database, and the last two states are expected to participate in the near future.

The database currently contains the results of over 3.25 million drug residue samples. Review of the data indicates that less than one tenth of one per cent of tankers of raw milk test positive for drug residues. Positive milk is disposed of under the direction of the state regulatory agency.

PESTICIDES

Pesticides, in general, follow the same scheme as new animal drugs in that pesticides require approval--in this case, registration and review by EPA--prior to use. Because they are intentionally applied to various food crops during or after cultivation, pesticides are generally not considered "contaminants" in the same sense as environmental pollutants, such as PCBs or toxic metals, which may become incorporated into foods unintentionally.

EPA, FDA, and USDA share responsibility for the Federal regulation of pesticides used on food or feed. EPA registers pesticides sold or used in the United States or permitted in foods offered for sale in U.S. commerce, and establishes tolerances, which are the maximum amounts of pesticide residues that may legally remain in or on raw agricultural commodities and processed foods. FDA enforces compliance with EPA's tolerances by sampling and analyzing both domestic and imported food to determine whether any pesticide residues remaining in or on the food conform with established limits. USDA's FSIS carries out this function for meat and poultry products.

Our program includes three types of monitoring, each with a different purpose:

- surveillance and compliance sampling, in which we collect and analyze samples of both domestic and imported foods for tolerance enforcement;
- the Total Diet Study, as described earlier; and

- incidence and level monitoring which has recently included statistical surveys of specific commodities to help estimate pesticide residue violation rates and evaluate whether surveillance and compliance monitoring results reflect the true incidence of pesticides in the food supply.

In designing our pesticide sampling plans, we consider factors such as the dietary significance of the food, the volume of the food in commerce, domestic and, as we have consistently informed GAO, foreign pesticide usage patterns, and the toxicity and chemical characteristics of each pesticide (such as persistence in the soil). We use a variety of both multi-residue and single-residue methods in each type of monitoring. We take steps to ensure that our chemical analyses are subjected to high levels of quality control and results are verified. We work with other Federal and state agencies to make our programs as complementary as possible, thereby ensuring the broadest possible coverage of the food supply.

FDA's pesticide monitoring program has three objectives: to uncover significant pesticide residue problems in both domestic and imported foods, to take enforcement action against food shipments found to contain illegal pesticide residues, and to deter future violations. FDA accomplishes these goals through its enforcement activities and by working with state and foreign governments to familiarize officials with U.S. laws and regulations pertaining to pesticide usage in food production.

As part of its regulatory monitoring, FDA samples individual lots of domestically produced and imported foods and analyzes these foods for pesticide residues. Commodities are examined in the form in which they move in commerce. If residues are found to exceed EPA tolerances or are found on a commodity for which no tolerance has been established, FDA has authority to invoke various legal sanctions such as a seizure of the food or an injunction. In addition, FDA has authority to refuse entry into the United States of imported foods that are or may appear to be adulterated.

Over the past five years, FDA has sampled and analyzed over 75,000 separate domestic and import food shipments for a wide variety of pesticide residues. Between one and two percent of the domestic samples and two to five percent of the import samples were violative. Of the approximately four percent of import samples that contained violative residues, the overwhelming majority had residues of pesticides that have approved uses and tolerances in the United States, but not for the particular commodity on which the pesticide residue was detected. [For example, there may be a U.S. tolerance for residues of a particular pesticide on white potatoes, but none for onions, and FDA finds residues of the pesticide on imported

onions. Under the FDC Act, the onions are adulterated.] Furthermore, the residue levels in these situations are frequently well below the U.S. tolerances set for the allowed commodity uses. For this reason, although these residues are illegal, we believe that the amounts found do not pose a significant risk to consumers. Approximately 1% of import samples contained residues of pesticides that exceeded U.S. tolerances, a violation rate similar to that of domestic foods. As mentioned previously, the Total Diet Study has shown consistently that the levels of pesticides in the U.S. diet do not represent a significant health risk to Americans.

In general, FDA's data over the past quarter century have demonstrated a very low violation rate and very low levels of pesticide residues in foods. We have not found evidence of major residue problems for pesticides that are used in high volume or ones that would be most likely to appear as residues because they are applied directly to the commodity. In fact, we firmly believe that pesticide residues in the U.S. food supply present very low risk to the public health.

Nevertheless, there are several areas in which the process for regulating pesticides could be improved to ensure even lower risk. This has been the topic at several previous hearings before other Committees, as well as the topic of several GAO reports. We would hope that the food safety reform legislation proposed by the Administration and currently pending before Congress (H.R. 4362 and H.R. 4329) will be enacted swiftly and, thus improve the ability of FDA, EPA, and USDA to carry out their respective roles for regulating pesticides, and better ensure that pesticide risks are minimized.

FDA prepares an annual summary of its pesticide residue monitoring program which is publicly available, and which has been provided routinely to GAO since it was first published. FDA will submit a copy of the 1993 summary for the record.

LEAD AND OTHER HEAVY METALS

Lead is a toxic metal with no known health benefit to humans. This metal, nevertheless, is incorporated into living organisms through its ubiquitous distribution in the environment (soil, air, and water). Most of the lead to which we are exposed stems from man's activities. Industrial emissions, effluents and discharges, by-products from the use of leaded gasoline, and, in some instances, community water supplies conducted through lead contaminated pipes, have been continuous sources of lead exposure.

A certain amount of lead is consumed in the food we eat, since both crops and animals may be contaminated from environmental sources. Lead also can enter the food supply from non-

environmental sources, such as food processing equipment, lead solder in cans, and leaching from ceramicware and crystalware.

Lead gradually accumulates in the body over a lifetime, residing primarily in bones, with smaller amounts accumulating in soft tissue. The risk to infants and children and to the developing fetus is of major concern because they are more susceptible to the effects of lead than are adults. There is growing evidence that lead affects growth and can cause learning and behavioral disorders in children even at low levels that were once thought to be acceptable. While levels are still elevated relative to non-industrialized societies, scientific evidence, including the Total Diet Study as discussed earlier in the statement, indicates that blood lead levels in the U.S. population have decreased significantly in recent years.

Lead Solder in Food Cans

In the 1970's, FDA launched a major lead control initiative to reduce lead in canned foods, which at one time contributed about one-third of the lead the average person obtained from food. Through a cooperative effort between FDA and the canning industry, the number of food cans containing lead solder was voluntarily reduced. According to the Can Manufacturing Institute, there are now no American-made food cans containing lead solder. To ensure elimination of exposure to lead from imported canned foods, FDA proposed, in June 1993, to ban the use of lead solder in all cans used for packaging foods. FDA also issued a rule establishing emergency action levels for lead in canned foods to address lead levels in imported canned foods until the ban can be finalized.

Lead in Ceramicware

Lead may enter the food supply from other food-contact surfaces as well. Lead may be a component in glazing materials used for ceramic dishes, bowls, pitchers, plates, and other earthenware. Many ceramicware products sold in the United States today are coated with glazes that contain lead. A glaze containing lead has to be heated, or fired, to a high enough temperature for a sufficient length of time to be sure it is safe. If glazes are properly formulated, applied, and fired, the final product will not release excessive levels of lead into foods contained in the ware. Lower quality or improperly fired glazes used on ceramicware can release unacceptably high levels of lead into foods contacting the ceramicware. FDA became aware of the problem of lead migration into food from pottery glazes in 1969 after a California family suffered severe lead poisoning from drinking orange juice stored in a pitcher purchased in Mexico.

FDA issued a compliance program in May 1971 to monitor foreign and domestic pottery for leachable lead. Under this program,

which is still in effect, FDA has inspected factories and analyzed samples from every major domestic manufacturer of ceramic dinnerware. The products of domestic manufacturers have relatively low rates for exceeding established limits for lead leaching. The Agency also routinely samples imported ceramicware. The violation rate for these products has been higher than that for domestic items. Items with lead levels that are too high are denied entry into the United States. FDA continues to work with foreign governments to develop agreements by which the foreign government ensures that ceramicware to be exported to the U.S. meets FDA guidelines for leachable lead.

In 1971, FDA established 7 parts per million (ppm) as the maximum permissible level for release of lead from ceramic foodware. FDA has since decreased the level further. The regulatory limits now vary according to the size and use of the product, and the potential for exposure to population groups at risk. For example, there is now an action level of 0.5 ppm for leachable lead from ceramicware pitchers, based on potential exposure of children who consume acidic beverages such as juice, which leaches greater levels of lead than non-acidic beverages stored in the pitcher.

Other Lead and Heavy Metal Reduction Activities

- FDA worked with a consortium representing a majority of crystalware manufacturers to reduce leachable lead from crystal goblets and decanters. Crystalware manufacturers agreed to share technology to reduce leachable lead levels in crystal, and established voluntary standards for leachable lead from crystalware and are monitoring for compliance with these standards.

- FDA established 300 parts per billion (ppb) as the level at which the agency would support enforcement actions by the Bureau of Alcohol, Tobacco, and Firearms against lead in wine. In November 1992, FDA proposed to ban the use of tin-coated lead foil seals on wine bottles, based on evidence that lead from the seals can leach into the wine. The majority of wine bottlers have ceased using foil seals in their packaging.

- In February 1994, FDA issued an advance notice of proposed rulemaking to obtain comment on the extent to which lead specifications for food additives, color additives, and Generally Recognized As Safe (GRAS) ingredients listed in the proposal can be reduced by use of Good Manufacturing Practices (GMPs). This list was developed following a food additive review to assess the impact of the population's total exposure to the additive and the average amount of lead contributed by this exposure.

- In May 1994, FDA published a final rule that reduced the maximum allowable limit for lead in bottled water from 50 ppb to 5.0 ppb. Since the source of most lead in water is from plumbing systems, manufacturers can control lead in bottled water through GMPs.

- In 1993, FDA issued guidance documents on cadmium, nickel, arsenic, chromium, and lead in shellfish. These documents are used by state and local officials to determine the public health significance of contaminants and assist them in issuing regional or local consumption advisories.

FDA will submit for the record a chronology of FDA's lead reduction activities and a list of regulatory limits for lead in various products under FDA jurisdiction.

DIOXIN

The dioxins of toxicological concern are a family of 75 related chemical compounds known as polychlorinated dibenzo-para-dioxins. Furans are a similar family of 135 related compounds that are known as polychlorinated dibenzofurans. Within each family, these compounds differ from one another by the number and position of chlorine atoms and in biological potency. Such chlorinated compounds are generally resistant to biological breakdown, and therefore, may remain in the environment for years. Dioxins are inadvertently produced through a number of activities, such as chlorinated bleaching of pulp and paper and incineration of wastes.

Some dioxins and furans, which are produced and widely distributed in the environment, are extremely toxic to laboratory animals. Foods are a vehicle of human exposure, and it has been estimated that foods, especially meat, fish, and dairy products (other than fluid milk), account for 98 percent of the human exposure to TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin), the most toxic of the dioxins. Our daily intake of TCDD from food sources has been estimated to be 0.04 nanogram per day. TCDD equivalents intake, that is, intake of TCDD and chemically related compounds, weighted by toxicity, is estimated to be 0.12 nanograms per day. A nanogram is one billionth of a gram. This extremely small quantity tends to accumulate in the body, particularly in body fat, and the normal body burden of TCDD is estimated to be approximately 50-100 nanograms. Again, this is an extremely small number. By comparison our normal body burden of lead is about a million times higher.

FDA has been active since the 1960's in developing analytical methodology to determine trace residues of dioxins and related compounds, conducting surveys of foods for these environmental contaminants, and taking appropriate action to minimize exposure to them. For example, in the late 1950's, fats and fatty acids

obtained as by-products from the slaughtering industry were found to contain unknown toxicants, later identified as dioxins, which caused outbreaks of chick edema disease. In 1960, FDA issued a Food Additive Regulation for fatty acids specifying that they should be free of chick edema factor in accordance with a 3-week chick feeding bioassay and later an alternate chemical screening test.

Since about 1980, FDA has been monitoring fish for dioxins. In the near future, FDA will issue a guidance document for dioxin in fish and shellfish that the states may use to issue advisories. In FY95, FDA will sample and analyze 4-5 types of dairy products for dioxin, in addition to other products, including fish.

In 1989, FDA confirmed Canadian findings of dioxin in milk and subsequently determined the primary source to be the paperboard container in which the milk was packaged. FDA worked with the paper industry, which has voluntarily modified the bleaching process to prevent or minimize the formation of dioxin. Currently the levels of dioxin from food contact papers is at or below 2 parts per trillion (ppt), which is very close to the limit of detectability of analytical methods for dioxin in these goods.

GAO REPORTS

I would now like to address, generally, the GAO Reports that are being released at this hearing: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158) and Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192).

First, we appreciate GAO's support for FDA's efforts to implement HACCP programs. As we stated earlier in the testimony, we believe that use of HACCP based systems for the food industry will underscore the industry's role in preventing food safety problems before they occur and enable food safety officials to make the most efficient use of existing resources.

GAO also supports the need for strengthening the enforcement authorities of the agency, for example, to provide for the authority to levy civil money penalties. The Administration's pesticide food safety reform proposal (H.R. 4362 and H.R. 4329) contains provisions to strengthen the FDA's enforcement authorities with respect to foods that contain illegal pesticide residues, and EPA's enforcement authorities under FIFRA.

We are concerned, however, that GAO's reports fail to acknowledge the numerous improvements which FDA has implemented over the last decade, many of which were made in direct response to previous GAO studies or Congressional concerns. While we agree that there are always improvements that can be made, we believe it is

important to acknowledge FDA's accomplishments over the last two decades, many of which are not reflected in these reports.

For example, the report stated that "neither EPA nor FDA has designed or managed information systems to promote access to and or use of available data." However, the data from FDA's Pesticide Monitoring Database has been given directly to GAO, and is routinely made available to both USDA and EPA, state agencies, and foreign governments. It is available to the public as well, through the National Technical Information Service.

FDA is also engaged in a longterm project to reprogram its tissue residue database into USDA's Residue Violation Information System (RVIS) software. FDA expects to complete this work in May 1995. The reprogramming effort will streamline data acquisition and make it easier for users to obtain information, generate reports, and track violations. Both agencies will have on-line access to the data, thus improving our communication in this area. Again, this updated information is not acknowledged in the GAO report.

Although FDA took steps to ensure that the agency's pesticide monitoring programs did not duplicate the pesticide collection activities of USDA under its Pesticide Data Program initiated in 1990, the GAO report does not reflect this. These are only a few examples.

Report on Chemical Residues

GAO states that fragmented responsibilities hinder identification of unsafe chemicals, and that inconsistencies between Federal agencies' risk assessments call these estimates into question. We disagree with this premise. The existence of different statutory authorities for FDA and EPA does not mean that risk assessments, performed under their respective legislative mandates are flawed. Differences in risk assessments for a particular chemical may be appropriate in light of what it will be used for, its toxicity, its potential route of exposure, etc. This issue has been raised by GAO in the past, and the agencies have cooperated to resolve this issue. The report does not acknowledge this cooperation.

Cooperation among the FDA, EPA, and USDA in other aspects of food safety monitoring has improved greatly in the last few years, with the most salient example being that of the Administration's pesticide food safety reform legislation. For the first time in the course of this debate, the three agencies reached agreement on a health based standard for pesticide residues in foods and ways to preserve access to agricultural production tools for American farmers while encouraging a reduction in pesticide use. This agreement also would resolve a major conflict between the standards for pesticide residues that currently exist under FIFRA and the FDC Act.

As mentioned previously, FDA and USDA are combining efforts in tracking residue violations by means of a joint database. I could provide additional examples, but I hope that I have made my point. Interagency cooperation has improved.

GAO also asserts that risk assessments by the various agencies are flawed because of insufficient data regarding food consumption and actual residues in foods.

We refer you again, however, to the discussion above regarding our Total Diet Study and Pesticide Programs. The data which FDA has gathered under the Total Diet Study for more than 3 decades provide a reliable picture of the residue levels in foods as they are consumed. In addition, FDA's statistical monitoring program, recently completed for tomatoes and pears, showed violation rates for these commodities that are very similar to those obtained through FDA's regulatory enforcement programs. While analysis of data pertaining to apples and rice are not complete, the violation rates for these commodities are also low and consistent with what is found in our normal surveillance activites. We believe these programs provide an excellent indication for consumers that there is a low probability of their receiving food that contains violative or unsafe residues of pesticides and chemical contaminants. As mentioned earlier, the data from the Total Diet Study are made available to both USDA and EPA.

We wish to point out that FDA continues to work directly with other countries regarding our requirements for imported products. We believe that these efforts, coupled with negotiations for international harmonization of requirements for foods and other products under Codex and other international agreements, will help to provide us with assurance regarding adequacy of the food safety and inspection systems of other countries. For example, FDA is working with New Zealand, Chile, and Holland on agreements covering the export of produce to the United States, and has nearly completed an agreement with Canadian officials regarding the safety of milk products that are traded between our two countries. FDA has also worked extensively with the Mexican government to ensure that products intended for U.S. markets are in compliance with U.S. requirements.

We also wish to take this opportunity to point out specific improvements that FDA has implemented with respect to testing of imported commodities for pesticide residues. FDA:

- developed and uses efficient multiresidue methods which can detect and measure residues of approximately half of the active ingredients of pesticides having food uses, and many additional metabolites. This figure includes pesticides known to be used in other countries, but which have no U.S. tolerances, and pesticides for which the U.S. tolerances have been revoked.

- has actively pursued acquisition of foreign pesticide usage data from commercial sources--Landell Mills Market Research, Battelle-Europe, and the Royal Society of Chemistry--as well as from governments of countries that are major food exporters to the United States, in accordance with the Pesticide Monitoring Improvements Act (P.L. 100-418, or PMIA). FDA uses these data to design the agency's national pesticide residue sampling plan, direct analytical methods development research, and target analysis for pesticide residues, focussing especially on those which have no U.S. tolerances.

- samples imported foods at a slightly greater rate than domestic foods, relative to their prominence in the U.S. diet, and emphasizes imported fresh produce.

- works directly with foreign pest control and food safety officials to familiarize them with U.S. laws, regulations, and enforcement practices and to encourage the safe and responsible use of pesticides. Ultimately this will help reduce illegal residues of pesticides on imported foods.

- actively participates in other fora, such as the Codex Alimentarius Commission and its various committees, the goals of which are to achieve international harmonization of national tolerances for pesticide residues in food in order to protect the health of consumers and to facilitate international food trade; and the Joint Expert Committee on Food Additives (JECFA) which addresses issues related to natural toxicants.

As GAO notes, however, Federal resources to test imported foods have not kept pace with the growing volume of imports. FDA is also concerned that the agency will be unable to sustain these enhancements to the pesticide and contaminants monitoring programs.

We also point out, with respect to testing for animal drug residues, that FDA continues to perform research into developing analytical methodologies to detect violative residues of drugs which were approved years ago, and that our monitoring is targeted to look for problematic compounds.

GAO Report on Tissue Residues

GAO states that no U.S. regulatory limits have been established for heavy metal residues in meat and poultry.

It should be noted, however, that the absence of a tolerance for a contaminant does not mean that it is unregulated. FDA can and does make health hazard evaluations for contaminants that lack established regulatory limits on a case by case basis. We assure

you that if the agency becomes aware that a contaminant is recurring on a regular or frequent basis, we will take all necessary steps, including the establishment of appropriate regulatory limits, to protect the public health.

The GAO Report also criticizes the agency for failure to investigate all tissue residue violations, and for obtaining only 12 injunctions and one prosecution in spite of numerous violations reported by FSIS.

It should be noted that FDA's enforcement activities with respect to animal drug residues has been significantly increased during fiscal year 1994. During this period, FDA initiated 11 injunctions and issued 176 warning letters in addition to conducting one evidentiary hearing under Section 305 of the FFDCA. This enforcement activity has been the result of coordinated efforts by FDA, USDA, and the Department of Justice. I would also like to mention that there is a multiplier effect from these activities, particularly injunctions because they are widely publicized in the trade press and in speeches made by FDA staff at State and national meetings of food animal producers. As a result of these activities and the sampling done by FSIS, the number of violative animals detected have consistently declined since 1991, with 4339 violations in 1991, 4325 in 1992, and 3809 in 1993. We expect further decline as the message that action will be taken against violators reaches animal producers.

CONCLUSION

Mr. Chairman, I have tried to describe briefly the challenges faced by FDA in response to an expanding, technologically advancing food industry, and chemical residues in our food supply. I have also tried to present a picture for you of the existing system for regulating various chemical residues in food. While this system is not "broken," it could nevertheless benefit from some changes. We agree with the GAO recommendation that FDA adopt HACCP based systems for food safety, and we have taken some initial steps to implement such a system.

FDA believes the food supply is safe, and certainly safer than it has been throughout human history. We are committed to our mission of protecting the public health from unsafe and illegal chemical residues, and we stand ready to work with the Committee in addressing these important issues. I hope that the information that I have provided today will assist you in your efforts to review Federal food safety programs.

My colleague and I would be pleased to answer any questions you may have.

Mr. TOWNS. Thank you, Dr. Shank.

Dr. Sundlof.

Mr. SUNDLOF. Thank you, Mr. Chairman and members of the committee. My name is Steve Sundlof and I am the Director of FDA's Center for Veterinary Medicine. Accompanying me today is Dr. Bert Mitchell, who is Director of CVM's Office of Surveillance and Compliance.

I assumed this position on June 12, 1994, and so like Mr. Taylor, I am fairly new to the system.

I would like to take this opportunity to tell you a little bit about my background and the vision that I have for CVM. It was my strong interest in residue prevention and my commitment to food safety which originally attracted me to CVM. This is an organization for which I have a great deal of respect.

I am a veterinarian and I also hold a Ph.D. degree in toxicology. Prior to joining CVM, I spent 14 years on the faculty of the College of Veterinary Medicine at the University of Florida, where I taught pharmacology, toxicology and food safety to veterinary students. My research interest focused almost exclusively on drug and chemical residues in animal derived foods with primary emphasis on prevention of these residues.

Because of my interests I maintained extensive interactions with USDA, FDA, and to a lesser but significant degree, EPA. I was a primary contributor to several of the livestock quality assurance programs that focus on responsible drug use and residue prevention. I have authored books and numerous scientific papers on drug and chemical residues, and was a codeveloper of a USDA-sponsored national data base on residues, drugs, pesticides, and environmental contaminants. Enough about me.

Traditionally, CVM has worked closely with FSIS in establishing residue monitoring prevention and enforcement programs. I intend to continue this relationship and encourage even greater cooperation between our two agencies.

FDA's testimony emphasizes many of the programs for which CVM and FSIS share responsibility. These include the development of a shared interactive information management system called the residue violation information system and cooperative programs to monitor the use of animal drugs, identify in proper use, and take action to prevent further adulteration of the food supply.

The mission of CVM, as I see it, is to ensure the safety of the food supply and to provide for the pharmaceutical needs of animals through the approval of safe and effective animal drugs.

My vision for the center is to establish a regulatory environment which encourages animal drug research and development, while maintaining our high standards of safety, quality, and effectiveness.

There are legitimate drug needs out there which are not being met simply because the cost of the approval process is prohibitive. Some of these needs are being met through the sale and use of unapproved drugs. By reengineering our approval process, we hope to encourage more companies to invest in the approval process rather than to market unapproved drugs.

In this respect, we will continue to increase enforcement action against the illicit sale and the use of unapproved animal drugs in

an effort to discourage practices which lead to foodborne residues and serve as a definite disincentive as the GAO report points out for companies to invest in research and development needed to take a drug through the approval process.

We will assist in the development of producer quality assurance programs that focus on food safety and safe drug use.

As center Director, I will encourage the cooperative efforts with USDA to develop educational programs which promote responsible drug use.

We will encourage preharvest food safety initiatives which support on-farm HACCP principles.

We will continue cooperative efforts with FSIS to develop and validate newer, more rapid and less costly analytical methods for detecting drug residues.

And finally, we will strive for constant improvement toward our continuing commitment to the safety of the food supply.

I appreciate the opportunity to present this testimony and I would be happy to answer any questions you may have.

Mr. TOWNS. Thank you very much, Dr. Sundlof, for your testimony.

Dr. Goldman.

STATEMENT OF LYNN R. GOLDMAN, M.D., ASSISTANT ADMINISTRATOR, PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. GOLDMAN. Good morning. I am pleased to appear before you today and to contribute to your continuing review of the Federal food safety programs.

As you have requested, I have limited my oral remarks to 5 minutes to provide a brief overview of EPA's programs to regulate and prevent illegal or unsafe chemical residues and contaminants in the Nation's food supply. But as requested by your committee, the written statement includes comments in a number of other areas.

Mr. TOWNS. Your entire written statement will be included in the record.

Dr. GOLDMAN. Great, and I will be happy to answer questions in any of these areas.

EPA's primary responsibility under FIFRA is to assure that pesticides will not pose any unreasonable adverse effects when used according to label directions. For food use pesticides, EPA's registration decisions are integrally linked to establishment of tolerances or exemptions from tolerance requirements. The pesticide tolerances established by the EPA are enforced by the FDA for most foods and the USDA for meat, poultry and some egg products.

We work closely with the FDA and the USDA, and one of our responsibilities is to make sure that there is a laboratory method to find the residues. We rely on FDA and USDA monitoring data in making our future decisions about a pesticide.

Tolerances generally reflect the maximum levels of residues that we allow to be present on the raw agricultural commodity when they enter commerce or at the farm gate. This level at the farm gate is generally much higher than the level that is actually present on food.

We believe that the tolerance process is just generally protective of the public health and that it is grounded in traditional risk assessment and risk management practices. However, we are continually looking for ways to improve our process based on evolving science and the need for more clarity and the use of the best available information that assures food safety.

In 1993, the National Academy of Sciences released a report, "Pesticides in the Diets of Infants and Children," that criticized our tolerance-setting process as being inadequately protective of children. As a pediatrician, I found their recommendations to be of particular concern.

There are two improvements in the data available for setting tolerances that were recommended. One was improved food consumption data for children to focus on age-specific dietary patterns, and the second was improved data on pesticide residues that are actually found on the food to enable EPA to test our own assumptions.

We worked closely with USDA and FDA to carry out these recommendations. Both USDA and HHS are exploring ways to expand their nutrition surveys and to make them compatible to help accomplish these ends.

The FDA has led an effort with USDA, EPA, and the National Food Processors Association to establish a uniform pesticide residue data base that would be established at the EPA. The plan for this data base is now completed and we must now identify how we are actually going to bring this about.

In addition, we are coordinating closely with FDA and USDA on a wide range of issues, particularly those related to analytical chemistry for pesticide residues.

As you know, the administration has placed a high priority on revising the Nation's food safety laws to strengthen them and remedy current inconsistencies. We believe that pesticide legislative proposals address many of the concerns mentioned by GAO in their report.

Our proposal would create a single strong health-based standard that would apply to all pesticide residues in food. We are seeking to replace the contradictory pesticide food safety standards in FFDCA, with a single health-based standard of a reasonable certainty of no harm, which would end the applicability of the Delaney Clause to pesticide residues.

The establishment of tolerances for thousands of fresh fruits and vegetables uses would provide public health protection for all pesticide uses on all foods. FIFRA would continue to involve risk benefit balancing, however.

We also have proposed enhanced enforcement authorities for FDA to recall and embargo violative foods and to level civil penalties. FIFRA recordkeeping on pesticide use would also be strengthened.

The legislative proposals also include a number of provisions regarding exports. In particular, we are proposing increased technical assistance to strengthen other countries' capacities for regulating pesticides. HACCP systems for imported foods are best achieved when the source country has a strong pesticide regulatory system.

We are also proposing strengthening some of our export provisions for pesticides to ensure that banned pesticides in the United States cannot come here on foods.

In closing, we are proud of the accomplishments of the Federal agencies charged with protecting the Nation's food supply. At the same time we acknowledge that improvements can and should be made. We have undertaken a number of administrative initiatives and we have proposed legislative changes to address many of the issues identified by the GAO.

We want to work with Congress for enactment of these needed reforms without delay.

I appreciate the opportunity to testify before you here today. And I am looking forward to your questions.

Thank you.

[The prepared statement of Dr. Goldman follows:]

STATEMENT OF
LYNN R. GOLDMAN, M.D.
ASSISTANT ADMINISTRATOR
OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
COMMITTEE ON GOVERNMENT OPERATIONS
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 1994

I. INTRODUCTION

Good morning, Chairman Towns and Subcommittee members. I am pleased to appear before you today and contribute to your continuing review of Federal food safety programs. As you requested, I will testify on the Environmental Protection Agency's (EPA's) programs to regulate and prevent illegal and/or unsafe chemical residues and contaminants in the nation's food supply.

EPA has an enormous responsibility with regard to pesticides. Recognizing that pesticides are biologically active chemicals and can have substantial risks associated with their use, EPA must above all assure that these products are being used safely. Further, it is incumbent upon the Agency to find ways to reduce the overall risks associated with the use of pesticides. At the same time, these chemicals have become basic tools in America's abundantly productive agricultural industry, and EPA in partnership with the U.S. Department of Agriculture (USDA) has a responsibility to provide American farmers access to the tools and methods they need to produce the food and fiber consumers depend on. We are proud that the United States food supply is among the safest in the world. At the same time, we must continuously seek to identify and eliminate any vulnerabilities to food safety.

In this testimony, I would first like to explain briefly the statutory, regulatory, and administrative requirements and procedures that are in place to minimize the vulnerability of the nation's food supply - both domestically produced and imported - to illegal, unacceptable and/or unsafe chemical residues and contaminants. This summary will include a brief discussion of the complementary roles of EPA, USDA and the Food and Drug Administration (FDA) at the Federal level. Second, I will provide an overview of the findings of the recently released EPA dioxin study as they relate to the safety of the food supply. Third, I will discuss the recent misuse of the pesticide chlorpyrifos-ethyl on cereals. The fourth section of my testimony will address the recently released General Accounting Office (GAO) report "FOOD SAFETY: Changes Needed to Minimize Unsafe Chemicals in Food" and the approaches we support to improve current practices as part of our comprehensive food

safety legislative initiative. The Administration's food safety initiative will create a unified Federal approach to the regulation of pesticides.

II. PESTICIDE REGISTRATION, TOLERANCE-SETTING, AND ENFORCEMENT

STATUTORY AUTHORITIES FOR PESTICIDE REGULATION

The registration of pesticides, establishment of maximum residue levels (tolerances) in foods, and related activities are the responsibility of EPA's Office of Pesticide Programs. EPA's pesticide regulatory authority derives from the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA). FIFRA governs the registration or licensing of pesticide products, and the FFDCA governs pesticide residue levels in food and feed crops.

REGISTRATION UNDER FIFRA

Pesticides are broadly defined under FIFRA to include insecticides, herbicides, fungicides, rodenticides, disinfectants, plant growth regulators, biological agents and other substances intended to control pests. Pesticide registration is a pre-market review and licensing program. No pesticide may be sold for use in the U.S. unless it is registered by EPA and bears an EPA-approved label that includes identifying information, warning or precautionary statements, and detailed directions for use.

FIFRA gives EPA the authority and responsibility for registering pesticides to ensure that when used according to label directions, they will not pose unreasonable adverse effects to the environment. It is a violation of the law for any person to use a pesticide in a manner inconsistent with its label, including the specified uses. FIFRA defines the term "unreasonable adverse effects" as "any unreasonable risk to man or the environment taking into account the economic, social and environmental costs and benefits of the use of the pesticide." Thus, FIFRA requires EPA to balance the risks and benefits of a pesticide in deciding whether or not to grant a pesticide registration.

State agencies play a primary role in pesticide enforcement under FIFRA, and many states have enacted their own legislation with additional enforcement authorities and greater penalties for violations. In addition, USDA and EPA both have responsibility to work with farmers and other pesticide users on the proper use of and alternatives to pesticides. To assist in carrying out their statutory roles, EPA and USDA signed a Memorandum of Understanding in August 1994 on research, technology transfer, and registration of new alternatives for important pesticide uses that may be lost due to regulatory action or as a consequence of

pesticide manufacturers' decisions to discontinue support for particular pesticides or pesticide uses.

In a typical year EPA reviews over 5,000 registration submissions that vary from routine label changes to the review of new active ingredients. Most registration-related submissions are for amendments to existing product registrations and for new formulations containing active ingredients already registered with EPA. EPA receives about twenty applications for registration of new active ingredients each year. Registration for a new active ingredient requires a significant investment in time and money by the registrant, as well as EPA. For example, data development for a major agricultural chemical can cost the registrant ten million dollars or more and take several years to complete.

EPA bases registration decisions primarily on an evaluation of test data provided by the pesticide applicant. Depending on the pesticide and its intended use, EPA can require over 100 separate studies for registration of a new pesticide. These studies provide data relating to potential toxic effects on humans (such as skin and eye irritation, cancer, birth defects, or reproductive system disorders); environmental fate (or how the pesticide behaves in the environment); ecological effects (toxicity of the pesticide to birds, fish and other non-target organisms), as well as other potentially harmful effects of pesticides. When a chemical is identified as potentially risky, we may ask for a number of additional studies.

For pesticides used on food, EPA's registration decisions are integrally linked to establishment of tolerances or exemptions from tolerance requirements. The tolerance-setting process is described in the next section.

TOLERANCE-SETTING UNDER FFDCA

Before a pesticide can be registered for use on food or animal feed crops, EPA must establish appropriate tolerances or exemptions from the requirement of a tolerance for pesticide residues in food or animal feed under the FFDCA. EPA establishes tolerances and exemptions under authority of the FFDCA to ensure that consumers are not exposed to unsafe pesticide residues in food which pose an unreasonable risk.

Tolerances generally reflect the maximum level of residues we expect to be present on raw agricultural commodities when they enter commerce (the "farm gate"). This practice has ensured that farmers using registered pesticides in accordance with EPA-approved labeling will not be found in violation of having over-tolerance pesticide residues. The farm gate level is generally much higher than the level eventually consumed in food, creating an additional margin of safety.

The pesticide tolerances set by EPA are enforced by the FDA (for most foods) and USDA (for meat, poultry and some egg products). FDA and USDA monitor domestically produced and imported foods in interstate commerce. U.S. tolerance regulations apply equally to domestically-produced and imported foods. If pesticide residues exceed an established tolerance or no tolerance exists, the crop is adulterated and is subject to seizure, regardless of whether the pesticide use is permissible in a foreign country.

EPA must answer three questions before establishing a tolerance. First, what is the chemical residue and how can it be identified? Second, how much residue will be found on the treated commodity? Third, does the residue represent a level which gives sufficient protection to public health?

The answers to the first two questions are derived from residue chemistry data, including plant metabolism, residue field trials, analytical methods and processing studies. The toxicity data required for registration are used to assess what potential adverse effects could be caused by dietary exposure to the residue. EPA then conducts a dietary risk assessment that combines residue chemistry and toxicity data with information on likely exposure levels, derived from surveys of food consumption. EPA's dietary risk assessments may use more refined estimates of exposure that are lower than tolerance levels, since tolerances represent the maximum residue level.

Before establishing a tolerance, EPA must reach a conclusion that under the proposed conditions of use, will protect the public health taking into account that exposure may last a lifetime. In the absence of reliable data, EPA uses conservative "default" assumptions in assessing potential exposure and risk. We also look at risks to significant subpopulations, as well as the population as a whole, using the Dietary Risk Evaluation System (DRES). DRES allows EPA to assess risks to subpopulations grouped by age, sex, ethnic and geographical background. We are working with USDA to improve food consumption surveys and refine our assessments.

Two different provisions of FFDCA govern tolerance setting. Section 408 requires the establishment of tolerances, or exemptions, for all pesticide uses on raw agricultural commodities. Most tolerances are established under Section 408. For pesticides used in food processing, or in cases where residues are expected to concentrate during food processing, food and/or feed additive tolerances are needed under Section 409 of FFDCA to prevent processed foods from being considered adulterated. Section 409 contains the "Delaney clause," which specifically provides that, with limited exceptions, no pesticide food additive may be approved if it has been found to induce cancer in humans or animals. Unlike FIFRA registrations and

section 408 tolerances, the Delaney Clause specifies a "zero-risk" standard that does not consider the level of risks, or benefits, in setting tolerances. A strict literal interpretation of this zero-risk standard for food additive pesticide residues was recently upheld by the United States Court of Appeals for the Ninth Circuit in the case Les v Reilly. The court held that the Delaney Clause bars tolerances for carcinogenic pesticides in processed food without regard to the degree of risk.

The Administration has proposed legislative changes to the Delaney clause to remedy inconsistencies in current law and apply a single health-based standard to all pesticide residues in both raw and processed foods. A summary of our comprehensive pesticide/food safety proposal is appended to my testimony. We want to work with Congress to achieve prompt enactment of these important reforms.

Data for Setting Tolerances

In July 1993, the National Academy of Sciences (NAS) released a report "Pesticides in the Diets of Infants and Children." The NAS criticized EPA's tolerance setting process as being inadequately protective of children. Two improvements in the data available for setting tolerances were recommended: (1) improved food consumption data for children to focus on age-specific dietary patterns; and (2) improved data on pesticide residues actually found on food to enable EPA to test its own assumptions. EPA has worked closely with USDA and HHS to carry out these recommendations.

The USDA's Human Nutrition Information Survey and HHS's NHANES could potentially provide complementary information to develop age- specific food consumption data. Both USDA and HHS are exploring ways to expand their surveys, and make them more compatible to accomplish these ends.

The FDA has lead an effort with USDA, EPA and the National Food Processors Association (NFPA) to establish a uniform pesticide residue database that would be established at the EPA. The plan for the database is completed; we must now identify the resources available and begin work on the database.

IMPORTED FOODS

Frequently questions arise about the applicability of tolerances to imported foods. I want to clarify that all pesticide residues in food, regardless of origin, are subject to EPA tolerance requirements. Foods containing residues not covered by a tolerance (or exemption) may not be legally marketed in the U.S. FDA enforces these requirements at ports of entry. Although tolerances are generally established in support of registration, EPA can also establish tolerances for imported

commodities for pesticide uses that are not registered in the U.S. These tolerances are often referred to as "import tolerances" and may be appropriate, for example, when a pesticide is used to control a pest that is not a significant problem in this country, or may be used on a crop not produced here. Some importation tolerances are established because the pesticide is not marketed in the U.S. The information used to establish an import tolerance is the same as that used in support of a tolerance for commodities treated within the U.S., and must provide EPA with the data needed to assess potential dietary risks. In addition, a petition for an import tolerance should briefly discuss the conditions of use of a pesticide in the country in which it will be used and present evidence that the requirements for use in the foreign country have been met.

CONCLUSION

In summary, the tolerance process is protective of public health in that it is based on conservative risk assumptions and is generally grounded in traditional risk assessment and risk management practices. The Administration has proposed legislation to provide greater assurance of food safety, by establishing a single, health-based standard for residues in all types of food, and requiring a specific safety finding for infants and children in all tolerance actions (see attachment).

The legislative proposals also address the issue of export of pesticides. As indicated in the attachment, export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) would be prohibited, as would export of any pesticide that has been denied registration or administratively or voluntarily canceled for all or virtually all uses in the U.S. based on health concerns, or those pesticides that were voluntarily canceled in U.S. by the manufacturer for health or safety reasons. Never-registered food use pesticides could only be exported if there were a U.S. tolerance for the active ingredient and/or a method capable of detecting residues in food. EPA would require anyone exporting a pesticide to comply with the UN/FAO code of conduct for pesticide distribution and use. Finally, the proposal authorizes funds for technical assistance to countries to strengthen pesticide regulatory programs, with particular emphasis on developing countries that are major exporters to the U.S.

II. EPA's DIOXIN STUDY

On September 13, 1994, EPA released a "public review draft" of its dioxin reassessment. More than 100 EPA and outside scientists worked for over three years to develop the current draft of the reassessment. Over the next 120 days, EPA will be taking public comments on the draft document. Early in 1995,

EPA's Science Advisory Board (SAB) will conduct a formal scientific peer review. We will conclude the reassessment about a year from now, incorporating changes as appropriate from the public comments, peer reviewers and the SAB.

Dioxins are a group of chemical compounds inadvertently created through a number of activities including: combustion, certain types of chemical manufacture, chlorine bleaching of pulp and paper, and other industrial processes. Dioxin is produced in very small quantities compared to other pollutants (around 30 pounds annually); however, because it is also highly toxic, it has been treated as a significant environmental pollutant since the early 1970's.

In 1985 EPA published a scientific review of the health effects of 2,3,7,8-TCDD (tetrachlorodibenzo-p-dioxin), the most toxic of the dioxin family of compounds. That assessment serves as the scientific basis for dioxin risk estimates for all EPA programs. The draft study not only updates the 1985 document, but also represents an ongoing process to build a broad scientific consensus on dioxin's toxic effects.

Regarding health risks, the draft study reaffirms the association between dioxins and cancer. In its 1985 assessment, EPA concluded that dioxin is an animal carcinogen and a probable human carcinogen. The review published this month reaches the same conclusion, but with greater confidence. Based upon both animal and human evidence, EPA's estimate of dioxin's cancer potency is essentially unchanged from that of 1985.

The draft reassessment differs significantly from the 1985 document in its evaluation of dioxin's non-cancer effects. Today we have a stronger body of evidence to suggest that at some dose, dioxin exposure can result in a number of non-cancer health effects in humans. These effects may include developmental and reproductive effects, immune suppression, and disruption of regulatory hormones.

While the reassessment has been underway, EPA has continued to move forward in implementing dioxin control programs. Recent actions taken by EPA include proposing air emission standards for municipal waste incinerators, proposing stringent water effluent standards for pulp and paper mills and waste incinerators. No later than next February, EPA will propose strict air standards for reducing dioxin and other emissions from medical waste incinerators.

We believe that the pathway for exposure to humans is primarily via airborne dioxins that settle on plants and are then passed on through the food chain. The draft reassessment indicates that animal fat is the major dietary pathway of dioxins. I want to stress, however, that EPA and other food

safety agencies and experts continue to believe that the benefits of a balanced diet, including increased consumption of fresh fruits and vegetables, far outweigh any theoretical risks from dioxin exposure. Following Federal guidelines to reduce intake of fat, especially saturated fats, will decrease dioxin consumption but much more effective are measures to reduce dioxin emissions.

In an effort to increase our understanding of dioxin, we are calling on all parties to submit data voluntarily. EPA is requesting that industry, public interest groups, state and local governments, academia, and hospital facilities examine their files for data pertaining to dioxin sources, releases and levels in air, water, soil, food, animal feed, and human tissues. In addition to this voluntary call-in of existing data, EPA is calling on industries that are potential dioxin sources to voluntarily work with the Agency to devise and implement emissions testing programs.

While the science of the reassessment is undergoing peer review, EPA will be examining the reassessment's policy implications to determine what additional changes, if any, are needed in existing programs. Existing EPA efforts and programs will not be changed on the basis of this draft reassessment; however, they may change significantly after the completion of the peer review. This spring, EPA will hold dioxin policy workshops to explore the policy implications of the reassessment. The details of these workshops will be announced later.

The reassessment represents a major expansion of EPA's scientific understanding compared to our previous assessments of dioxin toxicology. Once it has completed peer review sometime next year, this report will give us the best scientific basis possible to guide our continuing efforts to curb dioxin risks.

III. CHLORPYRIFOS-ETHYL ON CEREALS

I would like to spend a few minutes on a subject which is fresh in everyone's mind: the misuse of chlorpyrifos-ethyl incident.

Last May, FDA sampled oats at two Iowa feed distributors and reported a preliminary finding of chlorpyrifos-ethyl residues to EPA. Chlorpyrifos-ethyl is not registered by EPA for use on oats, and there is no tolerance for residues on oats. The contaminated oats were traced to the General Mills company. In June, FDA notified EPA of the misapplication of chlorpyrifos-ethyl to approximately 21 million bushels of stored oats at General Mills. Four million of the bushels had been processed into General Mills cereal products.

The residues were the result of an unauthorized use of this pesticide by a pesticide applicator under contract to General Mills. The contractor had, unknown to General Mills, substituted less expensive chlorpyrifos-ethyl for a similar pesticide -- chlorpyrifos-methyl -- which does have a tolerance on oats and is used to fumigate oats in storage to prevent insect damage.

Fortunately, in this case, the outcome was not tragic. Information available to the FDA and EPA indicates that consumption of oat products, containing the low levels of chlorpyrifos-ethyl detected, do not present a health hazard. This is especially good news for children as cereals, such as "Cheerios," are often a major part of toddlers' diets.

The chlorpyrifos-ethyl misuse continued for more than a year, in part, because no system was in place at the industry-level to monitor raw materials or finished food products. FDA samples about one to two percent of the food supply to verify compliance with tolerance levels each year with particular focus on likely problems. State agencies and USDA also conduct residue monitoring. Even with increased resources, however, regulatory agencies will never be able to monitor or guarantee the absolute safety of the entire food supply. Regulatory agency sampling must always be complemented by industry efforts to ensure compliance with the law and EPA regulations.

In the complex process of bringing food from the farmgate to the dinner plate, there are many potential points for breakdown in food safety to occur. Conversely, there are many opportunities to prevent problems. Quality assurance testing of the oats before they were made into cereal could have prevented the processing of contaminated oats into breakfast cereals. It could have avoided raising concerns about food safety due to illegal residues and saved General Mills tens of millions of dollars. There is a lesson to be learned here. The risks to companies of not assuring food safety are large, in terms of loss of public confidence, product liability, and monetary losses from contaminated merchandise. Companies cannot let down their guard when it comes to public health - especially the health of infants and children. One of EPA's guiding principles is to foster partnerships in the protection of public health and the environment. EPA is responsible for effectively communicating the Agency's goals and objectives for food safety. The food industry, in turn, are responsible for understanding their role in the process and maintaining a "watch dog" approach to ensure that incidents, such as the one with chlorpyrifos-ethyl misuse, are not repeated.

As explained in the next section, stronger and more consistent legislative authorities would help prevent the occurrence of unauthorized pesticide use by strengthening record-keeping, enforcement, and penalty provisions in FIFRA. The bill

would also provide additional enforcement authority and civil money penalties under FFDCA for foods adulterated with pesticide residues. In particular, penalties for pesticide misuse need to be increased. The applicator that applied the chlorpyrifos-ethyl has been indicted on eleven counts of mail fraud, and only one count of pesticide misuse, since the potential penalties for mail fraud are larger than for pesticide misuse (under FIFRA the maximum penalties are a warning letter for the first violation and a $5,000. fine for each subsequent violation). Any legislative reform package must include major improvements in enforcement authorities and a strengthened penalty structure under FIFRA.

IV. STEPS TO REDUCE FOOD SAFETY VULNERABILITIES

The new GAO report "FOOD SAFETY: Changes Needed to Minimize Unsafe Chemicals in Food" identifies weaknesses in Federal programs for monitoring chemical residues and environmental contaminants in food, and makes several recommendations to Congress. I would like to respond to some of these recommendations.

(1) Congress Should Enact a Uniform Set of Food Safety Laws

As you know, the Clinton Administration has placed a major priority on revising the nation's food safety laws to strengthen them and remedy current inconsistencies. We believe the legislative proposals address many of the concerns mentioned by GAO in its report. The pesticide/food safety reform package includes changes to both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Let me first mention some key elements of the legislative initiative that directly respond to GAO concerns:

- Our proposal creates one standard for approval and use of pesticides in food. The heart of the proposal is the establishment of a strong, health-based standard that would apply to all pesticide residues in food. We are seeking to replace the contradictory pesticide food safety standards in FFDCA with the single standard of "a reasonable certainty of no harm." As mentioned previously, the courts have determined that the Delaney clause must be interpreted literally by the EPA - that is, any level of cancer risk, no matter how small or how theoretical, precludes EPA approval of residue limits for pesticides in processed foods. We feel that this is an outdated standard that must be replaced. Existing residue tolerances would have to be reviewed and brought into conformity with the new safety standard within fixed time frames. The proposals allow for a transition period under carefully prescribed conditions

that will help avoid undue dislocations in agricultural production but still ensure an absolute deadline for all tolerances to meet the new standard.

- The legislative initiative also calls for periodic review and renewal of pesticide registrations and associated tolerances, on a 15-year cycle to ensure they are in conformity with current health standards.

- As mentioned in the previous discussion on chlorpyrifos-ethyl misuse, our proposals would provide additional regulatory tools, strengthen enforcement mechanisms, and increase penalties for violators.

- Improvements in FIFRA enforcement authorities would include enhanced inspection, record keeping, and lab audit authorities; "whistle blower" and citizen suit provisions; and significant increases in penalties for violations, commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

- Both FIFRA and FFDCA should explicitly recognize and require that changes made to one statute should be reconciled with complementary action under the other statute for issues relating to pesticide use on food.

- FDA should have enhanced enforcement authorities to recall and embargo violative foods and to levy civil penalties.

- We are also trying to reform cumbersome administrative procedures in FIFRA and give EPA new authorities - a label call-in provision and a phase-down provision so that we can take action short of suspension and cancellation of a pesticide.

The Administration's complete legislative proposal is summarized in an appendix to this testimony. Many of our proposed changes cannot be accomplished without legislative change. However, we have also undertaken a number of steps administratively, under existing authorities. These include:

- A new proposal "reinventing" tolerances, which was widely distributed in May of this year for comment, and should result in future rulemaking;

- developing a comprehensive approach to address the recommendations of the 1993 National Academy of Sciences study on "Pesticides in the Diets of Infants and Children;"

- giving priority to the registration and use of reduced risk pesticides; and

- working with USDA to increase use of Integrated Pest Management.

(2) Congress Should Consider Requiring that Imported Food be Produced under Equivalent Food Safety Systems

This is a recommendation Congress must review very carefully. While, under current law, meat and poultry products must be produced under equivalent food safety systems, these products normally come from central slaughter operations that can be continuously inspected. USDA has an inspection program that covers domestic meat and poultry and reviews systems abroad to assess their equivalency to the U.S. program. Monitoring foreign field-grown crops, such as fruits and vegetables, or requiring risk-based quality control systems for all imported foods, would present another challenge. Trade implications would need to be carefully considered. In establishing the equivalence of foreign food safety systems for crops, we would have to ensure that the imported food meets U.S. food safety standards, as well as ensure that the resulting system does not subject import food products to more stringent requirements than domestic products. We note that FDA has recently published an advance notice of proposed rulemaking to explore the feasibility of requiring risk-based programs for all food products.

V. CONCLUSION

In conclusion, we are proud of the accomplishments of the Federal agencies charged with protecting the nation's food supply. At the same time, we acknowledge that improvements can and should be made. We have undertaken administrative initiatives and proposed legislative changes to address many of the issues identified by GAO. We want to work with Congress for enactment of these needed reforms without delay.

I appreciate the opportunity to present this testimony and would be happy to respond to any questions you may have.

APPENDIX

ADMINISTRATION PESTICIDE/FOOD SAFETY LEGISLATIVE REFORMS: EXECUTIVE SUMMARY

In June 1993, the Administration announced its commitment to reducing pesticide use and promoting sustainable agriculture through the development of legislative, regulatory, and administrative initiatives.

The Administration's initiatives are designed to maintain and enhance food safety for all Americans, to address recommendations of a 1993 National Academy of Sciences (NAS) report on ways to improve pesticide regulation to better assure that children are fully protected from pesticide risks, and to strengthen regulatory agencies' ability to make and enforce sound, timely, science-based decisions to protect public health and the environment.

The Administration's pesticide/food safety reform package includes changes to both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The heart of the proposal is the establishment of a strong, health-based standard that would apply to all pesticide residues in food. Existing residue tolerances would have to be reviewed and brought into conformity with the new safety standard within fixed time frames. The proposals allow for a transition period under carefully prescribed conditions that will help avoid undue dislocations in agricultural production but still ensure an absolute deadline for all tolerances to meet the new standard.

The principles that guided our work in developing legislative and regulatory proposals included:

- a firm commitment to reducing risks to people and the environment that may be associated with pesticides, and especially to providing greater assurance of protection for children, while ensuring the availability of cost-effective pest management techniques;

- recognition of the need to work with American farmers to develop and implement improved means of pest control, to reduce use of high-risk pesticides and promote greater use of integrated pest management (IPM) techniques, including biological and cultural pest control systems and other sustainable agricultural practices;

- implementation of regulatory reforms and incentives for the development of pesticides that will eliminate or reduce risks.

Building on the recommendations of the NAS report and the input we have received from representatives of all interests concerned about pesticide use and regulation, we have developed a

comprehensive set of legislative reforms we believe will allow us to make real progress in enhancing public health and environmental protection. Consistent with the approach of the National Performance Review, these changes will make government work better, and establish a more credible pesticide regulatory system that is based on sound science and is capable of acting promptly to reduce pesticide risks whenever they are identified.

The major elements of the proposed reforms are outlined briefly below.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

- **TOLERANCE SETTING**
  Tolerances for pesticide residues in all types of food would be based on a strong, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. For carcinogens this standard represents an upper-bound risk of 1 in one million over a lifetime, calculated using conservative risk assessment methods.

  The statute would mandate use of the best available science and information in decision-making. In the absence of reliable information that could refine residue level estimates or other assumptions used in risk assessment, however, conservative default assumptions would be required.

  The statute would also specify criteria for the types of factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to potentially sensitive subpopulations.

- **SPECIAL PROVISIONS FOR INFANTS AND CHILDREN**
  Our proposals for tolerance setting are directly responsive to the NAS recommendations that EPA consider unique aspects of children's diets and other sources of pesticide exposure. EPA would be required to issue specific findings that a tolerance is safe for infants and children from potential pesticide risks.

  EPA would also follow the NAS recommendations of looking at multiple exposures when establishing a tolerance and vigorously pursuing more accurate data on children's consumption habits. FDA would prioritize monitoring of residues on the foods children eat most.

- **REVIEW OF EXISTING TOLERANCES**
  EPA would be required to review all existing tolerances and ensure that they meet the new standard within seven years of enactment.

Special **fast track** provisions would require priority review of pesticides which, based on currently available data, appear not to meet the safety standard. EPA would have to identify these pesticides within 180 days of enactment. The review of 75% of these tolerances will be complete within three years, and the review of all these tolerances will be completed no later than four years after enactment.

- **TIME-LIMITED TRANSITIONAL TOLERANCES**
  EPA could grant time-limited transitional tolerances of no more than five years for a pesticide identified during the tolerance review process as not meeting the safety standard, **if** the loss of the pesticide would result in significant disruption in the food supply.

  Under no circumstances would such time-limited tolerances be granted for pesticide risks that are an order of magnitude greater than negligible risk. The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on the tolerance sponsor to make the showing needed to support a time-limited tolerance, and to report biannually to EPA on efforts to reduce risks to negligible and the continuing existence of the effects that warranted the initial extension of the tolerance.

  A greater than a time-limited tolerance extended under these provisions could only be renewed if Congress enacted a statutory exemption.

  Both the tolerance review and transitional, time-limited tolerance provisions are responsive to NAS recommendations that tolerance setting be health-based, and that risk assessments incorporate improved toxicology and exposure data.

IMPROVED REGULATORY COORDINATION AND NEW ENFORCEMENT TOOLS

Both FIFRA and FFDCA should explicitly recognize and require that changes made to one statute should be reconciled with complementary action under the other statute for issues relating to pesticide use on food. Additionally, FDA should have enhanced enforcement authorities to recall and embargo violative foods as well as to levy civil penalties, and have access to certain pesticide-related records.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) PROPOSALS

- **REGISTRATION "SUNSET"**
  Pesticide registrations and tolerances must be renewed every 15 years to ensure they are in conformity with health

standards. This will apply unless a new application meeting current scientific standards is received by year 12 after registration and approved by EPA.

- **PHASE-OUT/PHASE-DOWN**
  Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or eliminating uses. EPA would consult with USDA in establishing phase-out requirements.

- **STREAMLINING LABEL CHANGES AND ESTABLISHING A SINGLE, UNIFORM LABEL COMPLIANCE DATE ("LABEL CALL-IN")**
  Modeled on the existing "data call-in" provisions of FIFRA Section 3(c)(2)(B), this authority would establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site).

  An annual uniform labeling effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

- **INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES**
  EPA would establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided in FIFRA.

  Also, EPA would be authorized to grant special time-limited conditional registrations for biologically-based pesticides posing low potential risks.

- **PESTICIDE RISK AND USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT**
  The Administration is calling for a joint EPA-USDA chaired effort to, within one year, develop commodity-specific pesticide use reduction goals.

  The statute would state a clear policy goal favoring reduced use and direct federal agencies to take a leadership role in promoting use reduction and IPM in their programs.

  The statute would authorize regional ecosystem-based reduced use pilot projects designed to reduce aggregate pesticide risks and set a goal for development of IPM programs and implementation strategies for 75% of acreage within 7 years

of enactment. EPA and USDA would be mandated to work together to identify the research, education and extension activities that are most promising in terms of opportunities for reducing use of pesticides that raise risk concerns.

The current prohibition on requiring IPM training as part of certification and training programs would be repealed.

EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pesticide resistance management programs.

- **IMPROVED PESTICIDE DATA COLLECTION**
  Following the model of the 1990 Farm Bill provisions, which require record keeping for restricted use pesticides, the Administration calls for record-keeping on all pesticide uses.

  EPA and HHS will continue to pursue better incident monitoring and surveillance systems.

- **PESTICIDE MINOR USES**
  Incentives for registering minor uses would include priority review and extended exclusive data use rights. In reregistration, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

  EPA, HHS/PHS, and USDA would collaborate to identify critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

- **CANCELLATION, SUSPENSION, AND TOLERANCE REVOCATION PROCEDURES**
  Cancellation and tolerance revocation procedures would be amended to replace formal, trial-type administrative law judge (ALJ) proceedings with a notice-and-comment cancellation process. Suspensions would be decoupled from cancellation procedures, and the time-consuming and cumbersome ALJ process for challenging suspensions would be replaced by a petition procedure and prompt judicial review.

- **ENFORCEMENT AUTHORITIES**
  Improvements in enforcement authorities would include enhanced inspection, record keeping and lab audit authorities; "whistle blower" and citizen suit provisions; and significant increases in penalties for FIFRA violations,

commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

- **PREVENTING EXPORT OF PESTICIDES BANNED BY EPA**
  Export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) would be prohibited, as would export of any pesticide that has been denied registration or administratively or voluntarily canceled for all or virtually all uses in the U.S. based on health concerns or those pesticides that were voluntarily canceled in U.S. by the manufacturer for health or safety reasons. Never-registered food use pesticides could only be exported if there were a U.S. tolerance for the active ingredient and/or a method capable of detecting residues in food.

- **FEES TO SUPPORT FIFRA '88 REREGISTRATION**
  The proposal would include authority to impose a new one-time supplemental reregistration fee assessed on an active ingredient basis and an individual product reregistration fee. Annual maintenance fees as required under the current reregistration program would continue.

Mr. TOWNS. Thank you very much, Dr. Goldman. And let me just say that on behalf of the committee, we look forward to working with you to improve the situation.

I think it was said early on, that when the subcommittee got involved in reinventing Federal food safety we were going to stay with it until it was done.

I think that we can and must improve in a lot of areas and that is what this committee is saying and why we continue to be so involved in this issue.

Dr. Shank, if the system is not broken, as you say, how do you explain 110 million boxes of adulterated cereal reaching consumers? How could such gross adulteration of a popular food product go undetected for over 1 year? How do you explain that if the system is not broken?

Dr. SHANK. Mr. Chairman, let me talk just a little bit about that situation. We, the FDA, identified this illegal pesticide through our normal surveillance sampling. And during our normal surveillance sampling, we don't have the same priorities on some of those that we may have on some of the other tests that come into our laboratory.

Even in view of that, within 30 days, we had identified the source of these oats. We had contacted the company and the company was in a position to take action. It was only 4 days between the time that we had completed our tests and when the company responded.

So I think that from identification of the problem until corrective action was taken, it represents a relatively short period of time.

You said, why did we not discover this problem during the year that it persisted. Again, I think it is important to recognize the situation that went on and some of the facts that have been mentioned here earlier today. This is not the normal situation you would find within the food industry where you have a contractual agreement and that agreement seems to have been violated.

Second, why didn't FDA catch it earlier? We don't have the resources to get around to each one of these firms on an annual basis. The comfort that we would have is that this was not a public health concern.

But I would hasten to add that in those pesticide residues or other problems where there are public health concerns, the industry generally pays increased attention under those situations.

Mr. TOWNS. So you are saying that the Federal food safety system is not broken, just not working? I am trying to make certain I have understood you clearly.

Dr. SHANK. I am saying that it was unfortunate that there was a year that expired between when this problem started and when it was found by the regulatory agency. I can assure you that from my understanding at least, the system that they have in place today, that HACCP system for that particular company will catch that type of problem in the future.

Mr. TOWNS. Dr. Goldman.

Dr. GOLDMAN. Yes, I think it is an example of how a HACCP system could be effective for dealing with pesticide residue issues. Right now, we rely on our label directions in order to control which pesticides are used on which foods.

But if companies were monitoring their own processes at critical points and keeping careful records, and as many companies do actually today, the kind of episode as the episode that happened with Cheerios could be totally prevented.

Mr. TOWNS. Do each of your agencies agree with GAO that the Federal approach of relying on end product testing to monitor chemicals residues in food cannot prevent problems from occurring?

Dr. GOLDMAN. I would agree. I think that the primary prevention needs to happen from the very point of use and through the whole process and not just by monitoring at the very end of the process.

And as I said, certainly our registration system is one way that that happens. But obviously, I think there needs to also be attention paid to the process throughout the entire production process.

Dr. SHANK. We too would agree with that conclusion, and as I said in our brief opening remarks, we feel that there is a better system and we are moving in that direction.

Mr. TOWNS. Let me raise the question with you, Dr. Sundlof. GAO testified earlier that only 1 out of about 21,000 animal drug residue violations that USDA referred to FDA over a 4-year period resulted in prosecution. And there is a problem of repeat offenders.

Now, I know you were not the center Director during those 4 years. You joined FDA on June 12, 1994. But in July of this year, "Food Chemical News" quoted you as saying—and I want to make certain we got this right—"We want to look less like a strong enforcement agency and more like an agency that is responsive to its customers."

Were you quoted accurately? And if you were, how could FDA look any less like an enforcement agency, given this prosecution record? I mean, just one? Were you quoted correctly?

[The article follows:]

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SUNDLOF WILL EMPHASIZE WORKING WITH INDUSTRY AS CVM CHIEF

New Food and Drug Administration Center for Veterinary Medicine Director Steven Sundlof has pledged to try to work out problems with industry before issuing regulations or Compliance Policy Guides, he told FOOD CHEMICAL NEWS July 5 (See FOOD CHEMICAL NEWS, June 13, Page 2).

Sundlof said he wanted to do more outreach to industry. "If we see a need for a Compliance Policy Guide because there is some activity out there that we just can't live with, our first approach is going to be to get with the specific industries that are causing the problem and try to get them to adopt more responsible standards (voluntarily)," he said.

If voluntary standards are unworkable, the agency would issue a CPG, but "before we make decisions we are going to try to get more input from those parties that are affected by the decisions, in order to get more 'buy-in' so there is ownership among the people we regulate," Sundlof said.

"I think a lot of times in the past we've just made decisions and hit them with it — 'here it is, deal with it,'" he continued. Instead, CVM should be presenting the problem to industry and asking for advice on a solution, Sundlof said, adding, "We want to look less like a strong enforcement agency and more like an agency that is responsive to its customers."

"The biggest immediate challenge facing me is to try and get everybody within CVM to work toward the same goal, and that goal is the understanding that the drug approval process is our means or the engine that drives food safety," he emphasized.

"Prior to this time, I think we've been very focused on ensuring that bad drugs are not allowed on the market, and that's not going to take us to where we want to be," Sundlof said. "It is not enough that we keep bad drugs off the market, we must encourage and facilitate the entry of new drugs into the market."

New Management Structure at CVM

Sundlof has altered the management structure at CVM so there will be two deputies. Dr. Richard Teske will be in charge of the Office of New Animal Drug Evaluation and the Office of Science, and Dr. Michael Blackwell will be in charge of the Office of Surveillance and Compliance and the Office of Management.

Sundlof said he changed the structure because "I was frankly just overwhelmed by the amount of material that gets passed through the offices ... that I felt really required more individual attention."

Sundlof: Increasing Animal Drugs Helps Food Safety

"My understanding of what CVM does is that our No. 1 primary mission is that we are charged with ensuring the safety of the food supply — all other missions are secondary," Sundlof said. "Our other mission is to provide for the pharmaceutical needs for those animals that are entrusted to human care."

"We have one tool in order to serve both of those missions — the animal drug approval process," he continued. "Increasing animal drug availability is the vehicle by which we achieve food safety and meet the needs of the animals."

Sundlof said his vision of CVM is as an agency that "provides a regulatory environment that encourages research and development in the area of new animal drugs."

Flexible Labeling, Streamlined NADAs Are Ways to Cut Extra-Label Drug Use, Sundlof Says

"A lot of the reason that I'm here is the result of extra-label drug use and the problems that it causes," Sundlof said. " I don't think it should be an illegal act for veterinarians to use drugs in an extra-label manner ... and in that respect I guess I would support a bill that said it's not against the law," he added.

However, "having said that, extra-label drug use is a disincentive to the drug approval process, and I look at it in that light," Sundlof continued. "Providing an atmosphere that is more friendly to drug sponsors is a primary goal. Anything that we can do to provide disincentives to extra-label drug use will help out on the other end to (encourage) companies to invest in research and development."

The new CVM director said he saw the agency's current CPG on extra-label use as a "band-aid approach" to the problem of too few animal drugs.

In order to encourage more legal use of animal drugs, CVM is looking at approaches such as flexible labeling and streamlining drug applications to eliminate outdated or overly burdensome regulatory requirements. "We want to find out ways of making (applications) less expensive, take less time, and look for scientific ways of achieving the same results as far as data and efficacy are concerned," Sundlof said.

For example, the center is currently looking at ways to ensure that applications don't sit on a reviewer's desk when other reviewers can be working on other parts of the application, he explained.

Sundlof emphasized that the agency will be trying to base all its requirements on sound science. "I think that where we have problems making a decision is ... the gap between where the science ends and where a decision has to be made," he said, adding, "As we look down the road into the future, we hope that science will narrow that gap ... so that we will be able to know more precisely, through mechanisms, how a drug affects safety and be able to make better decisions based on that."

Resistance, Not Residues, Is the Issue, Sundlof Says

The issue of antibiotic resistance will become at least as prominent as that of drug residues, Sundlof said. Antibiotic resistance is "an issue I take very seriously; one that could have a major effect on food safety if it is not handled responsibly," he added

The data linking animal drug usage to human drug resistance "are not bullet-proof, by any means," Sundlof continued. "But if I'm going to bet one way or another, I'm going to bet in favor of human food safety every time. And so, until we have better science on this issue, I'm going to have to make the assumption that the veterinary use of antimicrobials is contributing to some extent to a food safety problem, and we'll do anything we can to minimize the development of resistance — but at the same time, balancing that against the pharmaceutical needs of animals."

User Fees Important for CVM

The long-awaited proposal on user fees for new animal drugs has yet to make its way out of the Department of Health and Human Services, but Sundlof said that the user fee structure worked out in the proposal will be very important.

The fee process would "help me as a manager because it mandates that we use performance criteria to evaluate how good a job we are doing, and includes things like how long it takes for an application to get through the system before there is a final decision for approval," Sundlof said.

"We're going to institute a lot of things, such as a refusal-to-file policy, which the industry is in great favor of because it will allow us to take a quick glance at the application, and if the data are clearly not in compliance with what is required for approval, we will send the whole package back before we waste our time trying to review an application that is obviously insufficient," he continued.

"So those kinds of things are going to be very beneficial to us from a management standpoint, and also because the user fee will be largely targeted at the drug approval area, so we can commit more resources to that process," he explained.

If user fees are mandated by Congress, a user fee structure could be up and running by next year, he said. However, if FDA pushes for the user fees on its own, it will probably take at least two years before the necessary regulations are developed, he said.

Expect Changes in Compounding Proposal

The center will be presenting a much-changed proposal on compounding in a half-day session on the issue being sponsored by the American Veterinary Medicine Association and the American Academy

of Veterinary Pharmacologics and Therapeutics today (July 11) in San Francisco (See FOOD CHEMICAL NEWS, Sept. 20, Page 4).

The proposal is "a lot different from the one we came up with in the draft policy," he said, adding that many of the changes are due to the compounding workshop held last September and the task force report that came out of that workshop. "We are going to be presenting some new information on how we intend to regulate compounding that I think is going to be very helpful to practitioners," he said.

CVM Working With Field on Drug GMPs

CVM has recently put together a task force with Office of Regulatory Affairs field personnel to look at the issue of whether or not Good Manufacturing Practices applied to human drugs should be applicable to animal drugs, Sundlof said.

"We are going to look at those issues as a high priority item on my agenda, and try to come up with some kind of plan that we can implement to determine which of those standards could be changed," Sundlof said.

The center is also working with the medicated feed industry on the controversial issue of prescription medicated feeds, Sundlof said, noting: "My concern is the development of antimicrobial resistance, and ... proper use of these ... antibiotics." A diagnosis or culturing sensitivity and a very good understanding of those conditions that would promote antibiotic resistance which most feed officials do not have may be needed, he said.

Sundlof said that most feed officials are not trained in these areas and do not have access to the right kinds of diagnostic tools, and therefore there is a potential for misuse of some antibiotics. "So we are going to be discussing what we can do to minimize the risk — whether it involves a prescription or whether there is another mechanism to effectively prevent overuse or misuse of these drugs," he said.

HACCP's Influence Will Be Felt at Production Level: Sundlof

Although the Center for Veterinary Medicine will not be involved with the main thrust of the government's move toward universal Hazard Analysis Critical Control Point (HACCP) systems for food processors, HACCP's influence will be felt at the production level, he said.

"If I were a processor ... my critical control point No. 1 is going to be to make sure the raw product that I get in meets my standards for quality and safety and wholesomeness. And that's going to force HACCP down to the farm level," Sundlof explained. "Where CVM can be helpful is that we've encouraged and will continue to encourage the quality assurance programs that are being developed."

●

DOCTORS DEBATE JAMA CAFFEINE, MISCARRIAGE STUDY

Two separate letters in the July 6 Journal of the American Medical Association questioned a McGill University study which found that "caffeine intake before or during pregnancy was associated with

Mr. SUNDLOF. Yes, I was quoted correctly. I think the context may be a little different than what you are perceiving.

As I mentioned in my testimony, what we are trying to do in order to change the dynamics of the drug residue problem is to encourage companies to come in on the front end to seek approval so that we don't have to take as many enforcement actions on the other end, which is the sale of unapproved or unlabeled drugs.

The enforcement action that I was talking about was not against the residue violations themselves, but was against those who would sell or distribute unapproved animal drugs.

Again, we feel that the best way of preventing future residues from occurring and the only way that we are ever going to get a real handle on this system is to make this regulatory process more accessible so that all animals that need drugs will be able to go through our approval process and will have the benefit of drugs that we will know up front are safe rather than have drugs appear out of need that aren't approved and cause us residue problems. We are much more concerned about the unapproved drugs than we are about the ones that are approved.

Mr. TOWNS. In other words, you are going to cut down on the amount of letters that you are going to write, because there is no enforcement.

Mr. SUNDLOF. We hope that those number of letters will—that we will have less letters to write because we will have less residue violations. We are trying to attack the root cause of residue violations, which in many cases is just the fact that there are not enough drugs to meet the needs out there. And if there were, we would not be dealing with problems of the use of these drugs in an irresponsible manner.

Mr. TOWNS. I yield to Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

I have a brief couple of questions, but I can't resist making the observation that I think a major problem in the food safety area has been demonstrated by the last two panels in that in the last two panels we had representatives testify from three different government agencies with responsibilities in this area: the Food and Drug Administration, the Food Safety and Inspection Service, the Department of Agriculture, and the Environmental Protection Agency.

And I am not in any way critical of the individual witnesses, I am just trying to point out that I think it has been shown here better than anything we could say that when three agencies divide the responsibilities for a certain goal, that that is an inherent problem. And I think we should be working toward the goal of one agency with this responsibility.

With respect to the situation that exists now, I want to ask to the Food and Drug Administration representatives, are there changes in the laws that would improve your ability to enforce current standards?

In other words, could we help you in the Congress by passing any change in the law that would give you greater ability to, for example, go after repeat offenders who you have cited by letter over and over again for contamination?

Dr. SHANK. We have—we are paying attention to the recommendations in the GAO report. There are quite a number of recommendations there for civil penalties and what have you.

I can state at this point that we unequivocally support the legislative changes that are contained in the pesticide legislation that is before the Congress at this point in time.

We also have—would support streamlining the establishment of tolerances under section 406. In other words, something other than a formal rulemaking procedure which is rather cumbersome. Those are some key areas that we think would help us from the foods perspective.

Mr. SCHIFF. I think I can speak for all members of the subcommittee that we would welcome specific legislative proposals from all the agencies that share this responsibility to assist you in streamlining the system and making it more effective while we have the present system in place.

I thank the witnesses, and I yield back Mr. Chairman.

Mr. TOWNS. Thank you very much.

I yield at this time to Mr. Sanders.

Mr. SANDERS. Thank you, Mr. Chairman, and congratulations for holding a hearing on a very important topic, and my apologies for being late.

I think as somebody who has been a little bit involved in one aspect of this issue and that has to do the approval process for Monsanto's BST, let me say that I think we are being very naive this morning. If anyone thinks that the Federal Government can stand up to Monsanto Chemical Co., then we are just kidding ourselves.

Monsanto has put $500 million into the production of a product that really nobody wants. This is a synthetic hormone that increases milk supply. The result of the increased supply would be to drive the family farmers off the family farms. It makes cows sicker with mastitis and farmers have to use more antibiotics.

There was just a piece, I think, on CBS yesterday which talked about a farmer in upstate New York having to have his herd slaughtered because they were made sick by that particular product. Nobody wanted this product, except Monsanto. They poured in $500 million and the FDA caved like a house of cards.

I am sorry that Mr. Taylor is not here right now. Is he coming back or is he gone?

Mr. TOWNS. No, he is testifying in another hearing.

Mr. SANDERS. Mr. Taylor—unfortunately, I did want to speak to him a little bit.

The absurdity of the situation is that you had Mr. Taylor writing the interim guidance on labeling for the FDA, and maybe Dr. Shank can tell us who the former employer of Mr. Taylor was. Do you happen to know?

Dr. SHANK. He was with a private law firm here in town.

Mr. SANDERS. That is right. And who did that private law firm, and he in particular, represent? Just out of curiosity, might you know that fact?

Dr. SHANK. I am not sure who all their clients are, but——

Mr. SANDERS. Who was the client?

Mr. TOWNS. Let me say to my colleague that Mr. Taylor did testify earlier and he was just sitting on this panel. If you have specific questions, we could raise them with him in writing.

Mr. SANDERS. Obviously, the answer is he worked for a firm called King & Spalding, a major law firm, and his particular client was Monsanto.

Why should we be surprised that he represented Monsanto and he works for the FDA, who is presumably trying to regulate Monsanto's BST?

In November 1990, GAO released a report, "FDA surveys not adequate to demonstrate safety milk." This report criticized the FDA's monitoring of chemical residues like antibiotics in milk.

Could you please tell me what changes the FDA made to correct the problems discussed in that report of November 1990 and what changes still need to be made?

Dr. SHANK. We have made several changes. We have put out more tests to look for additional drugs. We have implemented new monitoring programs that I mentioned earlier this morning.

We now have access to all of the data that are collected by local officials, State as well as the industry themselves. So we have further access to data.

We have enhanced our quality control program of how we do our own testing so we have taken a number of steps to better utilize the constrained resources that we have to deal with this most important issue.

Mr. SANDERS. How much testing do you actually do?

Dr. SHANK. I could—we—let me provide the numbers for the record, because there is a certain level of testing that is—that FDA does. There is another level of testing that is done by State officials. It is a complex program, as you know, with oversights. And I would be glad to provide those numbers for you for the record.

[The information referred to follows:]

Tests Performed on Milk by FDA, the States, and the Industry			
Fiscal Year	Tests by FDA	Tests by the States	Tests by the Industry
1992	479[1]	106,000 finished products tested for beta lactams.[2] 1.12 million beta lactam tests on individual milk producers' samples.[3]	3.6 million beta lactam screenings of bulk milk pickup tankers.[4]
1993	357[1]	106,000 finished products tested for beta lactams.[5] 1.2 million beta lactam tests on individual milk producers' samples.[6]	3.6 million beta lactam screenings of bulk milk pickup tankers.[4]
1994[7]	285[1,7]	47,326 finished products tested for beta lactams.[7] 725,000 beta lactam tests on individual milk producers' samples.[7] 1851 NDRMMP analyses performed by the States using quick test kits provided by FDA.[7,8]	2.4 million[7]

1. Testing done under the National Drug Residue Milk Monitoring Program (NDRMMP) by FDA's Denver laboratory for 8 sulfonamides, 3 tetracyclines, and chloramphenicol. Analysis for Beta Lactam residues was added in April 1992.

2. Taken from a survey of the states.

3. Under the Pasteurized Milk Ordinance, an individual producer's milk must be tested 8 times per year. (140,000 producers times 8 equals 1.12 million tests.)

4. An estimated 10,000 bulk milk pickup tankers per day are delivered and screened by the industry. (10,000 times 365 equals 3.6 million.)

5. Estimate based on previous survey of states (See footnote #2).

6. This figure includes the 1.12 million tests done on individual producers and an estimated 80,000 tests done by the states to monitor the industry testing.

7. 1994 data submitted to the National Drug Residue Data Base. These data are still coming in, and, and at the time of this report, did not include any data from California or Mississippi. FDA anticipates the total number of tests will equal the number performed in 1993.

8. 634 analyses for beta lactams, 181 for chloramphenicol, 5 for gentamicin, 904 for sulfonamides, and 127 for tetracyclines.

October 4, 1994

Mr. SANDERS. I would appreciate that.

In February 1992, the GAO released a report entitled, "FDA needs stronger controls over the approval process for new animal drugs." That report found that FDA's approval procedures didn't detect fraud in the data submitted in support of animal drugs applications.

Would you be so kind as to tell us what changes the FDA made to correct those problems discussed in that report and what changes still need to be made?

Mr. SUNDLOF. Since that report was issued, we have taken some legal action against some firms and individuals who were part of that fraud. We have held them to very strict controls such that we have not approved a drug from the one company that we know was guilty of committing fraud. And we are not——

Mr. SANDERS. Which company was that, as you understand?

Mr. SUNDLOF. That was American Cyanamid, and we will not approve a drug for that company until they can provide us with a program that we validate that ensures that the fraud will no longer exist in that company.

Mr. SANDERS. Let me ask anyone, Dr. Shank or Dr. Sundlof perhaps, a question. If right now cows get sick from BST—and they are now, as I understand it—the normal procedure is to have them sent off for slaughter. What procedures are currently in place to protect the public from residues of synthetic BST and other risky substances that are injected into the meat?

Mr. SUNDLOF. In the meat—currently, we don't consider it to be—BST to be a residue issue. There is no testing of BST, because we have found it not to be unsafe. That is for BST.

For the drug residues——

Mr. SANDERS. By the way, you have found that there is no testing for BST. Do you know that tests could be developed? There is evidence that suggests that they could be developed.

Mr. SUNDLOF. We don't believe right now that the tests that could be developed would be sensitive enough to detect the levels that would occur in milk.

Mr. SANDERS. Do you know that there are scientists that disagree with you?

Mr. SUNDLOF. There may be scientists that disagree with me.

Mr. SANDERS. My understanding is—and I am pretty sure I am right on this—that there are herds that are becoming ill as a result of BST injections. My understanding is that those cows have been taken to slaughter to be made into meat that we eat. What is the FDA doing about that?

Mr. SUNDLOF. Let me say that virtually all cows that are dairy cows eventually end up in the meat supply.

Mr. SANDERS. Right, but is there a concern that if cows are slaughtered because they are sick——

Mr. SUNDLOF. I don't want to speak for the USDA, but they have a testing program that looks at animals before they enter——

Mr. SANDERS. Not a testing program. If, as I understand is the case, as has been recently reported on national television, a herd was made ill by BST, that is what I understand the case to be. Is that your understanding?

Mr. SUNDLOF. I understand that the herd which you are talking about had some increased mastitis problems which resulted in the individual dairy farmer taking a lot of his herd, about—about 25 percent of his herd, and shipping them for slaughter.

Mr. SANDERS. Yes, that is my understanding.

Now, are you concerned that cows who were made ill by this particular synthetic hormone are now slaughtered and will presumably appear in our hamburgers apparently soon?

Mr. SUNDLOF. Let me tell you that we think that the incidence of problems associated with BST use in terms of the types of diseases that we are talking about here are relatively common diseases. They include mastitis, reproductive disorders. These are things that naturally occur on dairy farms and are one of the causes that cows no longer produce milk.

In this case, we are not convinced even that the BST that was used in this farm was the cause of the problems associated or those problems were not manageable.

Mr. SANDERS. Let me just conclude my remarks. As someone who as followed the BST thing for several years, to tell you that it was disturbing to see the degree to which the entire process was dominated by Monsanto. It was disturbing to me that at least three high-ranking officials in the food administration were former employees of Monsanto in one way or another, worked for Monsanto.

I think that the issue that you are tackling here today is a very, very difficult and important issue. And I think the Congress has got to begin to stand up and be vigorous and demand that the U.S. Government and its various representatives and agencies protect the interests of ordinary Americans against very, very large companies who could care less about human health and are primarily concerned about their own profit margins.

I congratulate you, Mr. Chairman, on the hearing.

[The prepared statement of Mr. Sanders follows:]

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Statement of Rep. Bernard Sanders (I-Vt)
Subcommittee on Human Resources & Intergovernmental Relations
September 28, 1994

Thank you Chairman Towns for holding this very important hearing. Consumers are becoming more and more concerned about synthetic hormones and chemicals in their food because many are dangerous to human health. In fact, baby boomers are expected to have shorter lifespans than their parents and part of the blame lies with the increased use of chemicals and animal drugs.

There is one animal drug that I am particularly interested in and that is synthetic bovine growth hormone, otherwise known as rBGH. For those of you that didn't see Eye on America on the CBS Evening News last night, it is a drug produced by a large chemical company called Monsanto. It has no therapeutic value; rather it is a "production drug" which is injected into dairy cows to force them to produce more milk.

There is a great deal of controversy surrounding this drug because we already have a milk surplus, it will force many small dairy farmers out of business, and it makes cows sick. Monsanto's own studies show a 50 to 75% increase in mastitis - an infection of the udder that produces pus in milk. Because rBGH makes cows sick, there is an increased risk of antibiotics in milk produced from cows injected with it. But the FDA concluded that it was a "manageable risk" and approved the drug.

The FDA does not require rBGH milk to be labelled as such and the onerous procedures for voluntary labelling have discouraged most producers. However, the vast majority of consumers want labels, so I have introduced labelling legislation. However, until consumers get the information necessary to protect themselves, it is imperative that the FDA do everything necessary to protect the public.

Now, the public and I have a long list of concerns relating to the approval of rBGH, not the least of which is that some key FDA employees did some work for Monsanto relating to rBGH. Therefore, at the direction of myself and Representatives Obey and Brown, the GAO is investigating potential conflicts of interest. However, that is not the subject of this hearing, so I will focus my questions on the issue at hand - the adequacy of FDA's and USDA's post approval monitoring processes.

However, if, as I suspect, the post approval monitoring process proves inadequate, I will demand that you take another look at the approval of rBGH.

Mr. TOWNS. Thank you very much, Congressman Sanders.

I yield to Congressman Mica.

Mr. MICA. Dr. Sundlof, did you say that you graduated from the University of Florida?

Mr. SUNDLOF. I graduated from the University of Illinois but I taught for 14 years at the University of Florida.

Mr. MICA. Anybody who has been associated in any way with the University of Florida obviously has impeccable credentials. No further need for any questioning.

Mr. TOWNS. I would assume that the gentleman went to the University of Florida.

Mr. MICA. Given the Gators' standing, and it happens to be my Alma Mater, I will turn my attention to Dr. Goldman, because I know that she has been looking forward to seeing me. She may be taking come extracurricular courses there.

Dr. GOLDMAN. Where do I sign up?

Mr. MICA. But, you know, one of the problems that I have seen repeatedly, being here just 20 months, is that all of our Federal agencies do in fact have limited resources. And those are taxpayer dollars. And I come from a unique perspective. I try to look out for the poor guy that is paying the bill for all of this, and also try to get the biggest bang for the buck.

Some of the evidence we have before us today in the report seems to indicate that even if we reorganized some of the approaches to protecting the public as far as monitoring unsafe chemicals in food, that EPA still doesn't have its act together as far as determining what are acceptable levels of risk.

And, in fact, it says chemicals posing similar risks may be regulated differently under different laws. So we don't even have our own Federal act together as far as what are acceptable levels.

What is the situation here? And you know, the testimony says EPA may not be able to provide FSIS with the most current information on chemical risks and tolerances. EPA is in the process of reregistering pesticides, but may not complete this test until 2006.

And one of my main interests is, again, risk assessment. Are we really approaching this in developing a risk assessment and cost-benefit approach that prioritizes the greatest dangers?

So there are two questions. One, what about EPA and other agencies's conflict in setting standards; and two, what is EPA doing to resolve some of the problems that are outlined in this report?

Dr. GOLDMAN. Let me talk it through. You know, as you know, there are two statutes that we operate under, FFDCA, the Federal Food, Drug, and Cosmetic Act, and FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act. And our first line of activity on a pesticide is a registration under FIFRA.

That allows us to review the essential data about not only on human health but also the environment, not only food safety but also issues such as worker safety, the safety of those who handle and use the pesticides.

And then——

Mr. MICA. But what about these conflicts with agencies as pointed out here—do we need to go back and consolidate authority to set these standards?

Dr. GOLDMAN. Well, I think it is important that the assessment of the risks for food consumption is based on the same data that we use to assess the risks for handling or using the pesticides around your home, for the other uses.

Now, under FIFRA, we use what is called a risk-benefit approach. We balance between the risks of the pesticides with the benefits to the users, such as the growers, of the pesticides.

Where we have standards that are at odds you are actually within the food legislation under FFDCA where we have three standards for food safety, three standards for setting the tolerance. And there we do run into situations where for the same pesticide, we may have different considerations.

If a pesticide is used on a process food, if it is a carcinogen, it falls under Delaney, which is one standard. If it is used on a fresh fruit and vegetable, if will not fall under Delaney. And that is a contradiction in the way that we assess the public health and the safety.

Now, the reregistration program, we would disagree with the GAO that it will not be completed until 2006.

Mr. MICA. What is your deadline? Now, again, in prioritizing the greatest risks, obviously there is some way to at least get some preliminary estimate of what the greatest risks are.

Dr. GOLDMAN. Yes.

Mr. MICA. What goals or timetable have you set; what can we expect?

Dr. GOLDMAN. If we are able to generate the fees that we need in order to complete the program, we can complete the program by the end of 2001. We have set our top priority on the pesticides that are used in foods. These are our so-called list A pesticides. For those we have received 8,846 studies. I have been told we have reviewed 6,649 of them, although maybe during this hearing we have reviewed a couple more.

Mr. MICA. Well, in this report you are also accused of not using the latest scientific data available. How do you respond to that?

Dr. GOLDMAN. That is what the re-registration process is about is updating the science data. And I think that there has been a problem. I don't want to mask over that. There has been a problem with the fact that there were decades that went by when the information that the agency had was not keeping pace with the science, which is why in 1988 it was necessary for Congress to pass the law that required us to do registration.

We are now bringing all the pesticides up to date with the latest scientific data and, I think that we are going to be able to do that as expeditiously as anybody could.

Mr. MICA. Well, I still have problems with EPA's performance in this area. Starting out—I know my time is going to expire here—with the overall performance of the agency, and its willingness to look at some of the risk-cost benefit approaches that we have talked about.

Since this is our last hearing, probably, before the end of the session, you can take back my message to the Administrator that I am still determined not to see her as a Cabinet Secretary—or EPA as a Cabinet level position—until and in fact the agency does adopt some type of reasonable risk assessment approach. And if we have

to go to battle piece of legislation by piece of legislation, which we have done so far, we will do it in that fashion.

And I think we will also have additional numbers after November in support of the reasonable, common-sense approach that I think the Congress is looking for and the American people know, the people who are paying the tab for all of this, that we do, in fact, have limited resources.

We can't put an inspector on every truck, as we heard with the Department of Agriculture, and we can't have an inspector in every plant continually, but we can address the real risk. We can do a better job in cleaning up the environment, and also addressing these risk problems to I think the greatest extent possible, again with these limited resources.

Maybe you will take that message back. And I look forward to working with you in the second round next year.

Dr. GOLDMAN. I should say on her behalf that we look forward to continuing to work with Congress to improve how we achieve public health protection in each and every one of our environmental laws that we carry out at the agency, and that we are as interested as you are in achieving the maximum amount of risk to the public in all the actions that we carry out. So we are looking forward to working with you on that.

Mr. MICA. Mr. Chairman, I ask unanimous consent that the record be left open for additional questions for this witness.

Mr. TOWNS. Without objection, we will leave the record open for 10 days.

Let me say to you, first of all, thank you for your testimony, and second, let me reiterate something that was said earlier.

Some people believed that after our first hearings on food safety we would go away. But I want to assure that you that is not the case. We want to work with you, but we are going to be on this, time and time again. We probably won't do another one this year, but we will probably be right back here the beginning of next year because we are talking about the safety of people.

I think food safety is not something that we can take lightly. I know we talk about not having enough resources, but I think that what we need to do is make certain that the resources that we do have are being used in the most effective and efficient way.

The fragmentation is unbelievable and we cannot afford the luxury of it. We have to bring it all together and put it under one umbrella and be able to hold an agency accountable for what needs to be done. And this committee stands ready to work with you and if there are some things on this side that we need to do, we want to do that. But at the same time, we do not want to be guilty of not doing anything.

I think if there is one thing here that is encouraging is the fact that Mr. Taylor is new. The fact that, Dr. Goldman, you are sort of new, and the fact that, Dr. Sundlof, you are new. Dr. Shank, we still want to work with you.

Thank you so much.

The hearing is adjourned.

[Whereupon, at 12:33 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

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