U.S. DEPARTMENT OF AGRICULTURE MEAT INSPECTION PROGRAM

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION

AND THE

SUBCOMMITTEE ON LIVESTOCK

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

MARCH 16, 1993

Serial No. 103–5

Printed for the use of the Committee on Agriculture

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U.S. DEPARTMENT OF AGRICULTURE MEAT INSPECTION PROGRAM

TUESDAY, MARCH 16, 1993

HOUSE OF REPRESENTATIVES; SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION; JOINT WITH SUBCOMMITTEE ON LIVESTOCK; COMMITTEE ON AGRICULTURE,

Washington, DC.

The subcommittees met, pursuant to call, at 10:05 a.m., in room 1300, Longworth House Office Building, Hon. Charles W. Stenholm (chairman of the Subcommittee on Department Operations and Nutrition) presiding, together with Hon. Harold L. Volkmer (chairman of the Subcommittee on Livestock).

Present from the Subcommittee on Department Operations and Nutrition: Representatives Stenholm, Sarpalius, Dooley, Inslee, English, McKinney, Bishop, Volkmer, Clayton, Holden, Lambert, Smith, Gunderson, Allard, and Ewing.

Present from the Subcommittee on Livestock: Representatives Volkmer, Stenholm, Holden, Long, Peterson, Dooley, Gunderson, Smith, Boehner, and Goodlatte.

Also present: Representative E (Kika) de la Garza, chairman of the committee.

Staff present: Andy Baker, assistant counsel; Julia M. Paradis, assistant counsel; William E. O'Conner, Jr., minority policy coordinator; John E. Hogan, minority counsel; Dale Moore, minority legislative coordinator; Glenda L. Temple, clerk; Stan Ray, Rob Wight, Tim De Coster, Dan McGrath, Curt Mann, Pete Thomson, and John Frank.

OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. Good morning. The hearing will come to order. Today, we are pleased to join with the Subcommittee on Livestock in our continued effort to review the Federal meat and poultry inspection system. We say "continued" and emphasize continued because although recent events have drawn significant attention to this issue, we have been working for many years to make significant, science-based improvements in our inspection system; but as many in this room are aware, this issue has historically been very contentious and complex and, unfortunately, we have not been as successful as we would have liked.

Overall, we have a very safe food supply at a very reasonable cost, that many of us take for granted in this country. I want to stress this point to the media here today. This hearing is not de-

signed to advance the cause of those whose interests are anything other than making responsible improvements in our inspection system. We are here today because this committee firmly believes that we have the most abundant and safest food supply at the lowest relative cost of any other country in the world, but we want to make it better. If improvements can be made to reflect our best available science, we owe it to the American consumers, taxpayers, and the meat and poultry industry to pursue those improvements.

It is in this context we believe our meat inspection system can and should be improved—brought into the 1990's based on our best science and technology. This committee wants to help make this happen.

It is our objective, and it is my objective as chairman of the Department Operations and Nutrition Subcommittee, to provide a forum for producers and consumers to begin talking to each other about this issue—finding common ground and mutual solutions. In my mind, that common ground should be based on the best available science, not emotional scare tactics and not standards founded on business as usual within the industry.

With that in mind, we begin the process today with a hearing that hopefully identifies the current situation and the science-oriented spectrum of options before us. As we roll up our sleeves and go to work, it is our intent that this merely be the beginning of a series of efforts that will lead to this joint subcommittee hearing and all interested parties ultimately addressing this issue and finally bringing it to a satisfactory solution.

Mr. Smith.

OPENING STATEMENT OF HON. ROBERT F. (BOB) SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. SMITH. Thank you, Mr. Chairman.

The recent *E. coli* outbreak, even though caused by improper cooking, points out the need to be vigilant about consumer confidence and food safety. It is clear that the current meat and poultry inspection system, while the best in the world, can be improved. Any improvement plan should be driven by sound scientific principles, and I agree with you, Mr. Chairman, on that very important point. It should not be driven by panic, peddling interest groups, not by the worries over labor relations nor media hype, and not as a method to tax the livestock industry unnecessarily.

So I thank you for bringing this subject to the Congress and our opportunity to look exactly at the issue and to listen to experts, whom we have here today, to discuss how we can indeed improve the inspection system and continue the consumer confidence that we have had held for the last 50 years.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Smith follows:]

STATEMENT OF ROBERT F. SMITH
BEFORE A JOINT HEARING
OF THE SUBCOMMITTEES ON
DEPARTMENT OPERATIONS AND NUTRITION
AND ON
LIVESTOCK
MARCH 16, 1993

I'd like to thank the Chairmen of the Livestock Subcommittee and the Department & Nutrition Subcommittees for calling this hearing today.

The recent E.coli outbreak in the Pacific Northwest, even though it was caused by improper cooking techniques, underscores the importance of remaining vigilant about consumer confidence in the safety of our nstion's food supply. It is a cliche that the Media always breaks the story on the front page, or on its flagship news program, but buries the objective analysis.

In any event, many observers believe that the current US meat & poultry inspection system, while easily the finest in the world, can be improved. Industry, academics, consumer groups and many in Congress think we can do even better.

Much of the Food Safety Inspection Service's resources are directed to the detection of animal disease. At the same time, 95% of all foodborne illness is caused, not by contaminants apparent to our senses of touch, vision and smell, but by bacteria.

The trick to successful change, and change is very popular these days, is to improve upon what you have without ruining it in the process.

The General Accounting Office is currently in the midst of conducting a study on our meat & poultry inspection system. This study should be completed in the summer. The Food Safety Inspection Service is developing a two-track approach, near- and long-term strategies to improve the system.

Since the Congress will have to enact any fundamental changes ultimately suggested, these two Subcommittees will have to monitor this discussion closely. At this stage in the process, I have a few criteria by which I will judge proposals.

Any improvement plan should be driven by sound scientific principles. We owe it to the taxpayers, the livestock industry and the consumer to continue providing the best inspection system in the world.

Our consideration of proposals should not be influenced by panic-peddling interest groups, whose objectives are defined by the next press release. We should design an effective inspection system, sensitive to the concerns of labor relations, but not determined by them.

We must avoid the temptations of media hype. Various news organizations have invested considerable hyperbole in this subject and will look for future opportunities to expand upon past performances.

And finally, we cannot use the goal of improving inspection as yet another method to tax the livestock industry. Meat & poultry inspection benefits all consumers and all should pay.

Mr. Chairman, I look forward to hearing the testimony of today's witnesses.

Mr. STENHOLM. Ms. McKinney.

Ms. MCKINNEY. Thank you, Mr. Chairman.

As a new member of the committee, and indeed of the House, I am here to learn the background on our country's inspection system. Because, Mr. Chairman, I have not been a party to or bloodied by the conflict of the past; I can say that my motives and my objectivity is as pure as I hope the food is that reaches the tables of America's families. Thank you.

Mr. STENHOLM. Mr. Allard.

OPENING STATEMENT OF HON. WAYNE ALLARD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Mr. ALLARD. Thank you, Mr. Chairman.

I would like to associate myself with the remarks made by the chairman and the ranking Republican member of this subcommittee.

I am a veterinarian and extremely interested in the proposals that you will be bringing forward. I do appreciate the fact that you are going to be stressing on scientific methods and being as objective as we possibly can in analyzing our current system in coming up with new procedures and perhaps better procedures than what we are using now.

I would also note for the record that I think the United States does have the safest food supply in the world. I do believe that there are things we can do to make it better, and we are here to hear that constructive type of discussion.

Thank you, very much, Mr. Chairman.

Mr. STENHOLM. All members may have additional statements inserted into the record at this time. I know we will be joined by others in just a moment.

[The prepared statement of Mrs. Clayton follows:]

PREPARED STATEMENT OF HON. EVA M. CLAYTON

Opening Statement for Food Inspection Subcommittee

March 16, 1993

I would like to take this opportunity to welcome the participants of today's hearing: Dr. Cross, Dr. Hughes, and Mr. Harman as well as our distinguished second set of panelists. We appreciate your candid remarks on this crucial issue under consideration today. Furthermore, we appreciate your contribution to the quality and welfare of our nation's food supply.

In recent days, the public has been frightened by the detection of infectious E. coli in ground meat. It would be an understatement to say that this is a menacing situation. Not only do my constituents deserve the knowledge that their food is safe to eat, but the American people deserve this peace of mind.

In the United States, we possess the very finest in technology and scholarly inquiry in regards to nutrition and food safety. It is my sincere desire that this committee work with the Department to facilitate a better effective system for regulating the food that we consume in this country.

Mr. STENHOLM. Our first panel will be Dr. Russell Cross, Administrator of the Food Safety and Inspection Service, U.S. Department of Agriculture, followed by Dr. James Hughes, Director, National Center for Infectious Diseases; and then Mr. John Harman, Director, Resources, Community, and Economic Division of the Food and Agriculture Issues, U.S. General Accounting Office.

Before I recognize you, Dr. Cross, I recognize the cochairman of this hearing, Mr. Volkmer.

OPENING STATEMENT OF HON. HAROLD L. VOLKMER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mr. VOLKMER. Thank you very much, Mr. Chairman.

We are pleased today to join with the gentleman from Texas and the Department Operations Subcommittee to begin our review of the meat and poultry inspection system. This will be an important series of hearings as we consider how best to modernize and improve the efficiency and effectiveness of the meat inspection process.

We recognize that we will have a limited amount of funds with which to run the program. We need to assure that our inspection system provides the greatest amount of protection for the money available.

As we consider the various issues to be brought up today and in future hearings, we need to keep in mind a few basic points: Regardless of the inspection process that is in place, we must recognize its limitations. We must make sure that consumers understand what the system does and what it does not do. There seems to be a general perception that the USDA's seal of approval means a product is absolutely safe, no matter how it is handled after inspection.

Of course, this is not true. Though we must be careful that the Government and industry do not inadvertently mislead the consumer as to possible health risks, we must also distinguish between what is technologically possible and what is practical and economically feasible.

We hear a lot about microbial testing, but clearly we cannot afford a system that would test each and every piece of meat for all of the scores of pathogens that might be present. We have to search for that optimum level of testing.

The area of microbial testing also begs the question of what we would do with meat found to contain one or more potentially harmful bacteria.

Many of these organisms can be destroyed simply by adequate cooking of the meat, so we surely would not condemn, unless there is severe threat to human health. But we have found the organism in the meat; what do we do? I will leave that question open to the witnesses.

As we, with you, explore the inspection system, we need to be cognizant of the operation of the regulatory system beyond inspection. How the meat is handled after it leaves the packer and before it sits on a plate, ready to eat, has a large impact on its healthfulness. The consumer does not care which Government agency is involved, USDA, FDA or State and local health authorities, so long as a wholesome product is placed before them.

Therefore, USDA must look beyond its own areas of responsibility in deciding how the inspection system ought to operate. The Department must take into consideration, as a practical matter, what is likely to happen to the meat after it leaves the inspection site. We must have coordination and communication between all the various links in the food safety chain.

Finally, I look forward to the challenge of meeting President Clinton's call to rethink Government, to improve the way Government works. No one is well served by an inspection system that is not efficient—not producers, not industry, and not consumers. We need to take a look at this program and see if there is a better way.

I think this meeting will be a good place to start that process. And I thank the chairman.

Mr. STENHOLM. Thank you.

Dr. Cross.

STATEMENT OF H. RUSSELL CROSS, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY JILL HOLLINGSWORTH, ASSISTANT TO THE ADMINISTRATOR

Mr. CROSS. Thank you, Mr. Chairman and members of the subcommittees, it is a pleasure to appear before you today to discuss our thoughts on the modernization of meat and poultry inspection. We very much appreciate your interest in improving our current program, and we hope that we can gain your support as we begin on what we are calling a revolutionary program to modernize the meat and poultry inspection program of this country. As always, your advice and comments will be appreciated as we move forward in this modernization.

1992 was a year of assessment for FSIS, a year of planning, a year of discussing, a year of looking back at what has worked for this agency and what has not worked for this agency since 1906. We have now positioned ourselves to make some tough decisions within FSIS about where this agency will go as we approach the next century.

We must take FSIS from an organoleptic inspection system that has evolved since 1906, to what we think has to be a science-based and a risk-based inspection system.

At the same time, we must continue to strengthen our current program to protect public health. Over the last 12 months, our agency has been involved in a number of planning activities for this jump into the future, and in January, as part of our ongoing strategic planning, we presented to Secretary Espy our proposal for a new two-track approach to the regulatory program of the future.

We recognize, as we look back to 1906, that we have been using the evolutionary approach to modernizing inspection. We recognize that the evolutionary approach was not working. Therefore, track I, in our proposal to the Secretary, will involve maximizing the performance of this current inspection system, whereas track II of this proposal will involve a totally new approach to designing and implementing the regulatory inspection system of the future.

As you know, shortly after we proposed this two-track strategy, we were faced with a food safety crisis, the *E. coli* 0157:H7 out-

break in the State of Washington. But this crisis did not change our strategy; our two-track proposal still remains in place.

However, we recognized immediately that we needed to zero in on the pathogen-control aspects of that two-track strategy. Therefore, we have developed and presented to Secretary Espy, a proposed pathogen reduction program to ensure that our pathogen reduction goals received the attention and the resources that they deserve.

The pathogen reduction program is a key part of track I and overlaps into track II.

Today, I would like to summarize for the subcommittees our two-track approach to inspection modernization. I would also like to briefly summarize the pathogen reduction strategy that we are proposing to implement immediately.

As we look at track I, which is maximizing the current inspection system, we have centered our planning and our strategy around six key elements, and the first key element is public ownership of what we do as an agency. Public ownership means actively involving all of our constituents, the public, consumers, the industry, the scientists that provide us the key information that we need, other Federal agencies and, don't forget, our own inspectors in the field. We have to involve these people and these parties, in an open decisionmaking process as we move forward.

For instance, we are proposing to seek public comment on our strategic plans for track I and track II through a series of regional hearings that we scheduled this spring. Hearings are tentatively scheduled to begin in Washington, DC, next month and are proposed for several other cities across the United States between April and June. We will be actively seeking grassroots information and reactions during these public hearings.

A second component of track I is agency staff and structure needs. We have to make sure that we are adequately staffed to meet the needs of meat inspection as it is designed today. We have to be certain that the agency is adequately structured to meet the mission today and tomorrow of meat and poultry inspection.

I recognize that there has been much discussion over the last few weeks as to whether or not we need the additional 160 inspectors President Clinton has proposed to be funded in his economic stimulus package. With all this discussion that has recently focused on pathogens that inspectors cannot see, we need to remember that our inspectors carry out important assignments to protect consumers.

For example, they inspect the animals before and after slaughter, looking for indications of disease; they examine carcasses for visible contamination that may carry or harbor bacteria and they also conduct on-site rapid testing of hundreds of thousands of samples to screen for chemical residues.

In processing plants, inspectors check such vital steps as thermal temperature to prevent botulism in canned foods.

The 160 inspector positions proposed by President Clinton would help meet the current legal requirements for inspection coverage. We cannot abruptly stop operating our current inspection system because we know it must be improved. We must be sure that the

current system does what it can and does it the best it can be done today.

A third component of track I, and a very important component, is labor relations. It is imperative for FSIS to build a strong and mutually supportive relationship with our employee organizations. We recognize that employees who are stationed in plants have practical knowledge of how our programs work or perhaps how our programs do not work. I am committed to the principles of total quality management and I will ensure that all of our employees are given the opportunity to participate in making decisions about changes to our inspection program now and in the future.

The centerpiece of track I, the current system, is our goal to reduce pathogens. We realize, as we strategize for our future, that pathogen reduction cannot wait until next year or next month. It has to begin now. I will elaborate on this pathogen reduction strategy momentarily.

A fifth key component of track I is consumer service. FSIS is proposing to intensify its health and education programs that positively influence food industry employee behavior to reduce foodborne illness. We are also proposing to expand our efforts to provide consumers with information on food handling and cooking, and this is also described in the pathogen reduction strategy.

And finally in track I, science and technology are absolutely critical for what we do today, and of course what we do tomorrow. We will make decisions based on science when it is available, but we will also not wait for all the i's to be dotted and t's to be crossed before we take advantage of new scientific information.

We have to be able to justify present and future inspection programs based on sound data. That data can come from numerous sources. It can come from universities, from industry, or from Government laboratories, but there is no question that we have to have that kind of data.

The regulatory program of the future, what we are calling track II, will be revolutionary, revolutionary in our thinking and revolutionary in the directions we take and recommend to the Secretary.

As we plan for track II, we intend to disregard current constraints, including budget and legislative authority. We want to look truly to the future.

We believe that the best strategy is to decide what works best and then decide what changes in resources and authority would be necessary to implement such a program. We must provide a vision of a public health, risk-oriented, risk-based food safety program that is not constrained within the configuration of the current program.

As I mentioned earlier, we tried the evolutionary approach, tinkering with the current program. It just has not taken us to where we think we need to be. We have to use a revolutionary approach and it has to be based on risk.

We also must identify what would be needed to support implementation of such a new system of inspection, including the mechanisms of program implementation, necessary changes in the law and resources, including people and money that will be required.

As a starting point at FSIS, we will host, this October, an international symposium on meat hygiene. At this symposium, we are

asking top government officials from over 30 countries to come together to describe their present systems and their thinking for the future. We want to hear how other countries manage the elements of their inspection programs, particularly in relation to pathogen reduction. We know we can't continue to live in a vacuum. We know we have to use any source of information worldwide as we plan this future track II system.

Shifting to our pathogen reduction program—part of track I—this program is designed to reduce the likelihood that harmful microorganisms, such as *Salmonella, Listeria, E. coli,* or *campylobacter,* will enter the food supply in the production, distribution, and consumption chain.

The plan the Department is now proposing is strongly based on HACCP principles and incorporates the essential elements of a diverse pathogen reduction approach. The pathogen reduction plan addresses eight key areas which I will very briefly highlight here.

The first is preharvest production. Working closely with our sister agency, the Animal and Plant Health Inspection Service, key universities, and private labs, we intend to find out why certain animals are more likely to be harboring pathogenic organisms than others. Because the research cannot tell us today with precision where and why these organisms appear, it has not been possible for us to design on-farm programs to make certain animals coming into the slaughterhouse are not the source of these dangerous pathogens.

Eventually, we need to be able to develop on-farm prevention systems. Eventually, HACCP has to go all the way back to the farm, and that system has to be controlled so that we can prevent the pathogens from entering into the food chain.

A second key area that is part of our plan is development of rapid methods. We think this is important because in order to reduce pathogens, we must be able to detect their presence at various points in the food production process. We have to be able to conduct research to develop methods to detect and enumerate microorganisms of public health concern in raw and ready-to-eat meat and poultry products and in live animals.

The third area is post-harvest activities, and it is designed to investigate what happens to bacteria during all phases of food processing and to design and test interventions that break up the chain of bacterial contamination.

As you know, or as the subcommittees may know, over the last year we have approved several intervention systems, such as organic acid washes, trisodium phosphate and poultry irradiation, these are voluntary systems available for the industry to use. We hope to approve more of these intervention systems as the science dictates that we can. We hope to continue to allow these voluntary systems to be used and in some cases they may have to become mandatory.

The fourth area, risk analysis, is very important to us. It is also very important to any food safety program throughout Government. It recognizes a sound scientific process is needed to assess the inherent risk of the current procedures that we conduct in our inspection program in terms of their potential for foodborne illness

and the value in the same terms of any intervention systems that we use.

We propose to adapt the science of quantitative risk assessment to foodborne hazards and to our inspection activities and, therefore, improve our agency decisionmaking process. I fully realize, as we look at risk analysis, and you hear different agencies within this Government talk about risk analysis, whether it be APHIS, CDC, or FDA, we all have to be speaking the same language. It is absolutely critical that we work together as we look down this risk-analysis path.

The fifth area, slaughter plant activities, reflects our commitment to proceed with activities that are likely to succeed based on current theories about pathogen control. We are proposing to introduce useful microbial detection technologies into the present system as they become available and not wait for a full complement of new rapid detection systems.

We will accelerate the introduction of HACCP strategies in the slaughter and processing areas as rapidly as possible. For example, in the slaughter area we intend to immediately expand the microbial baseline programs for cows, poultry, and swine. As you know, we began the microbial baseline testing on a national scale for steers and heifers last October.

These baseline studies are going to be used as one yardstick to see whether we are making progress as a nation, as an industry, and as a government regulatory program in reducing pathogens.

We will also immediately begin to test disabled cows to try to determine the source of these pathogens, comparing the disabled cows to the more healthy animals. We will also begin to immediately improve our slaughter procedures to reduce pathogens and physical contaminants.

As necessary, we will enhance veterinary coverage in the plants that kill the high-risk animals, the disabled animals, and animals more susceptible to disease. We will mandate more sophisticated recordkeeping by industry at the slaughter plants so we can facilitate traceback to the farm.

We will develop a microbial monitoring program for beef slaughter based on HACCP principles. Basically what that means is we will, in fact, be monitoring critical control points in the slaughter process for bacteria using existing techniques and using rapid methods as they become available.

We will then move to the sixth area, processing plant activities. We propose to improve current processing procedures that impact on the growth of pathogens. We will look at time and temperature control in the processing area; we will improve current processing procedures; and we will finalize the patty docket and controls on similar products with regard to cooking and handling.

We will mandate safe handling labeling for all raw meat and poultry products going to food service and retail.

Just as we plan for slaughter, we will develop a HACCP-based microbiological monitoring program in the beef processing plants as well. We will, in fact, this year, hopefully, be monitoring critical control points for bacteria.

Since we cannot ensure pathogen-free raw meat and poultry products in the future, food service and retail activities, we feel, are

critical to the pathogen reduction program. We will provide State and local public health authorities with current information on food safety requirements and methods of enforcement, working very closely with our sister agencies in Government.

We will also work cooperatively with FDA, USDA's Extension Service, and trade and professional organizations to identify the level of knowledge of food service workers in safe food handling practices and to prepare a joint HHS–USDA initiative to educate restaurant managers and staff based on this information.

Consumer awareness is our eighth strategy. We believe that food safety involves a farm-to-table agenda; we believe that everybody has a role in food safety, including regulatory agencies, the industry, and the public. Proper handling, storage, and preparation of these perishable products, we feel, is less widely known in contemporary households than it once was. Less time and attention are often devoted to these matters.

We propose to intensify our ongoing national consumer awareness campaign to improve the understanding of the risk of unsafe food handling practices, using ground beef safety as a key.

We will increase cooperative efforts with agencies and organizations who share roles as food safety educators. Certainly each of these initiatives, track I, track II, and the pathogen reduction program, have individual time lines we will follow to ensure that our goals are met.

I want to emphasize, however, that we are moving rapidly. These are goals that we intended to move forward with in 1993 and 1994.

I think with the tragic *E. coli* outbreak in Washington State, and a new administration, we are on a much faster time line than we were on January 1.

We plan to interact extensively with public health experts as we move forward in these strategies. For example, during the *E. coli* outbreak, we worked closely with the CDC, and we want that interaction to continue. In fact, we want to expand it.

Many of our plans will involve the Food and Drug Administration and other Federal agencies. We recognize the value of consistent policies emerging from various Federal agencies as well as the value of soliciting as many opinions, expert opinions, as possible.

Mr. Chairman, I hope this discussion of our two-track approach for planning the future of modernization of inspection and the pathogen reduction program provides a clear view of where FSIS is heading. We believe they form a cohesive strategy to meet the need for a modern, public health-oriented meat and poultry system of the future.

Mr. Chairman, and members of the subcommittees, this concludes my statement. I will be happy to answer any questions that you might have.

[The prepared statement of Mr. Cross appears at the conclusion of the hearing.]

Mr. STENHOLM. Dr. Hollingsworth, do you have anything to add at this time.

Ms. HOLLINGSWORTH. No, thank you.

Mr. STENHOLM. Next, we will hear from Dr. James Hughes, Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention.

STATEMENT OF JAMES M. HUGHES, M.D., DIRECTOR, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY MITCHELL L. COHEN, M.D., DIRECTOR, DIVISION OF BACTERIAL AND MYCOTIC DISEASES

Dr. HUGHES. Thank you, very much, Mr. Chairman, and members of the subcommittees. I am accompanied today by Mitchell L. Cohen, M.D., Director of Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Center for Disease Control and Prevention.

We are 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 by which CDC identifies foodborne hazards and characterizes 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. Although a foodborne illness can be brief and mild, it can also be life-threatening, causing miscarriage, hemolytic uremic syndrome, chronic kidney disease, arthritis, and death as evidenced by the recent outbreak of disease caused by *E. coli* 0157:H7 which contaminated hamburger.

During the past 15 years, we have learned a great deal about foodborne disease. We have identified previously unrecognized bacteria, such as *campylobacter, Listeria,* and *E. coli* 0157:H7 as common causes of foodborne disease.

All of these data suggest that foodborne disease is an ever changing public health challenge, a problem of emerging infectious diseases.

The Institute of Medicine recent report on emerging infections, identifies six factors which can lead to emerging microbial threats—changes in human demographics and behavior; technologic advances; economic development and land use; international travel and trade; microbial adaptation; and a breakdown of public health measures—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. Meat and poultry products have been recognized as an important source of foodborne disease. These products become contaminated during slaughter and processing, and when they are undercooked or mishandled, can lead to disease. Prevention of meat- and poultry-borne disease requires a coordinated program of risk assessment and risk management.

As the Nation's prevention agency, CDC has the knowledge, skills, and perspective critical to a comprehensive science-based program for foodborne disease surveillance, outbreak investigation, diagnosis, and prevention.

CDC's primary role in the coordinated Federal program to prevent meat- and poultry-born disease is that of risk assessment. The tools CDC has developed are the foodborne disease outbreak surveillance system, intensive epidemiologic and laboratory investigations of foodborne disease outbreaks, surveys and studies of specific

foodborne diseases, laboratory-based surveillance of specific foodborne microorganisms and analysis of strains of foodborne microorganisms submitted to our reference diagnostic laboratories.

The present system of foodborne disease outbreak surveillance began in 1966. Foodborne, as you recall, surveillance comprises the collection, collation, and analysis of data on foodborne disease outbreaks provided to us by State health departments.

In the past 10 years, approximately 5,000 foodborne outbreaks, involving 150,000 persons and 150 deaths, have been reported to CDC. Analysis of these outbreaks has proven valuable in characterizing the risk of foodborne diseases and documenting the efficacy of regulatory controls.

Another important source of epidemiologic data on epidemic foodborne disease, is CDC's emergency response to foodborne disease outbreaks. The large outbreak of *E. coli* 0157:H7 infections occurring earlier this year in the Western States represents a serious public health problem. In response to this outbreak, five CDC field teams with 14 medical and veterinary epidemiologists investigated the outbreak in collaboration with State and local public health officials and Federal agencies.

These investigations traced infections to consumption of hamburger, which led to a rapid product recall; limiting the size of the outbreak; a change in cooking requirements for hamburgers; identification of possible sources of implicated meat in order to change slaughter and processing practices that increase the risk of contamination; and identification of factors which need to be addressed to prevent person-to-person spread of infection in child day care centers.

Much of what is known about the emerging public health threat posed by this organism has been learned during CDC's response to outbreak investigations. Although our current surveillance systems and epidemic investigations are critical to our understanding of foodborne disease and its control, these two sources of information focus only on foodborne disease outbreaks. However, most foodborne diseases occur as isolated or sporadic events rather than as part of dramatic outbreaks. Human infections like *campylobacter jejuni* provide a good example of this phenomena.

In contrast to the outbreak data, studies by CDC and others suggest that poultry and not raw milk is the most common vehicle for the sporadic cases of *campylobacter jejuni* foodborne disease. Therefore, CDC needs to understand sporadic foodborne illnesses as well as outbreaks.

The epidemiology of sporadic foodborne disease is often defined by prospective studies. For example, after outbreak investigations demonstrated that epidemic *Listeriosis* was caused by eating specific contaminated foods, studies were established by CDC to evaluate whether all cases of *Listeriosis* were foodborne. These studies confirmed the foodborne nature of *Listeriosis* and led to specific relations for producers, consumers, and physicians for the prevention of this disease.

CDC and State public health departments have for many years used the public health laboratories to monitor specific foodborne microorganisms such as *Salmonella*. Isolates of *Salmonella* are

submitted to State laboratories for serotyping, and the results are transmitted to the CDC.

Public health officials use these data to recommend prevention measures at the State and national level and agricultural officials use them in educational programs for producers.

CDC has long maintained expertise in the identification and characterization of foodborne microorganisms submitted to its reference laboratories. Developing new and improved subtyping methods is an ongoing activity at CDC. CDC laboratories have also developed new subtyping schemes for *E. coli* 0157:H7, which have been instrumental in tracking the recent epidemic strain in meat and infected persons. This technique has been vital in defining the scope and the source of the outbreak.

Despite this impressive record of achievement, continuing hazards in our food supply tell us we must do better. We have identified four activities that will lead to better control of foodborne disease.

First, closer coordination with risk management agencies. CDC responds rapidly to requests from State epidemiologists for collaboration and leadership in investigating epidemics of foodborne disease. Through collaboration with the Food and Drug Administration and USDA's Food Safety Inspection Service, outbreak investigations frequently identify possible points of entry of pathogens into the food supply.

Further collaboration with USDA, FSIS personnel will augment our ability to investigate the slaughter and processing environment.

Second, strengthened surveillance for emerging human pathogens. Effective surveillance is key to identifying and tracking the prevalence of foodborne diseases. Such surveillance provides policymakers and health professionals with the basis for developing, implementing, and evaluating control policies. We are developing electronic surveillance systems that will make reporting from State health departments to the CDC more rapid, easier, and, hopefully, more complete.

Third, rapid and effective reaction to foodborne disease. Rapid and effective reaction requires a nationwide system in which public health laboratories in all States identify potential foodborne pathogens, electronically transmit the information to CDC for cluster analysis and interpretation, and rapidly relay appropriate microbial isolates to CDC for molecular epidemiologic studies.

CDC has developed a computer-based data management and reporting system, the Public Health Laboratory Information System, and is in the process of installing this system in all public health laboratories.

CDC is expanding and improving pathogen subtyping systems to identify case clusters and unusual events.

Laboratory and human resource needs in State public health departments must also be addressed.

Fourth, proactive foodborne disease prevention programs. Proactive foodborne disease prevention programs for recognized hazards require quantitative risk assessment and development of hazard analysis critical control point, or HACCP, plans for all foods and menu items. In the short term, an effective prevention effort

would include a program of geographically and demographically representative sites for intensive surveillance and investigation of acute human illness due to currently recognized high priority bacterial foodborne pathogens.

In the longer term, an expanded active surveillance program would be necessary to include additional infectious and noninfectious hazards, rapidly identify and characterizing 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 investigate the effectiveness of food safety programs and the impact of regulatory change.

To conclude, CDC has an integral role to play along with the FDA, USDA, and State and local authorities in the collaborative response to food safety issues. Improving food safety and meeting emerging foodborne disease problems in the 21st century will require a comprehensive program that will conduct surveillance to rapidly determine populations at highest risk, further document the important causes of foodborne disease, and identify new foodborne disease threats and more completely determine which products, processes, and practices led to foodborne infection.

Based on that information, effective educational programs for producers, processors, preparers, and consumers could be designed. Defining how foods become contaminated, developing rapid and accurate diagnostic tests for foodborne pathogens, and developing control strategies will minimize and prevent contamination of food by disease-producing microorganisms.

Thank you very much for the opportunity to discuss CDC's role in preventing foodborne disease. Dr. Cohen and I will be happy to answer any questions you or members of the subcommittees may have.

[The prepared statement of Dr. Hughes appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you, Dr. Hughes.

Next, we will hear from Mr. John Harman, Director of Resources Community and Economic Division, Food and Agricultural Issues, U.S. General Accounting Office.

John, welcome.

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 and members of the subcommittees. We are pleased to be here before the subcommittees to discuss the need for changing to a scientific, risk-based meat and poultry inspection system. The public interest raised by recent tragic events and the concerns about foodborne illnesses provides an opportunity to make these needed changes.

My testimony this morning is based on a great deal of work that has been done by us as well as others since 1977 on many of the issues that are being discussed here this morning and most recently also work that we are doing for you, Mr. Chairman, on the meat inspection system.

I will be summarizing my prepared statement, which is submitted to the subcommittees for the record.

The current meat inspection system which is based on a labor-intensive visual inspection does not provide the level of safety required by current threats. Unless changes are made, we face the risk of repeats of events that occurred recently.

Our inspection system must be changed so that the intensity and type of inspection coverage is based on the risk a particular food or processor presents. Such an approach has been advocated by experts for over a decade, and although recognizing the needs to modernize its inspection system since the late 1970's, FSIS has been hampered by the lack of a well-designed strategic plan, difficulties in achieving a consensus of all affected parties, and inflexible laws and regulations that lock the agency into the existing system.

Much has changed since many of these laws were enacted. Human health hazards posed by animal diseases have decreased while microbial hazards have increased and now present the greatest risk to public health. Our current inspection system has not kept pace with these changes and suffers from at least four significant limitations:

First, legislatively mandated continuous inspection frequencies drain resources and limit FSIS's flexibility to respond to changing risks; second, FSIS spends half of its resources on activities not related to safety which are out of line with its mission to ensure safe and wholesome meat and poultry; third, requirements and ambiguities in the law and changes in the food industry have resulted in inconsistent inspection treatment which erode public confidence; fourth, and most important, FSIS does not routinely perform microbial tests of equipment surfaces or raw products and does not require industry to perform such tests.

To change to a scientific risk-based inspection system, FSIS needs to develop and implement a clear and detailed plan for change; obtain a consensus for change by soliciting the involvement of all interested parties; and seek legislative changes to the meat and poultry inspection acts and congressional guidance on the objectives of the Federal inspection system.

In developing its plan, FSIS needs to research alternative inspection approaches. While hiring 160 new inspectors, as FSIS has recently announced, will help alleviate the load on the existing system and may help build public confidence, it will do little to address the underlying requirements of the current inspection system. FSIS should consider other alternatives and its plan should set out specific goals, identify the barriers to meeting these goals, develop countermeasures to identified barriers, set milestones and require periodic progress reports.

Even with a comprehensive plan, FSIS cannot achieve success on its own. Recent failed attempts to improve the inspection system illustrate the need for consensus on major changes.

Although representatives of the inspectors' union, consumers groups, and industry expressed optimism about the current FSIS administrator's efforts to improve communication and consider outside views in agency decisionmaking, mistrust, and other concerns remain.

Finally, modernizing a system that has survived largely unchanged for almost a century and forming a partnership among previously acrimonious parties will require strong leadership. Here we believe the Congress can play a vital and important role by providing the stimulus for change, strong support for agency management, and the vehicle for change through new legislation that provides the flexibility needed to target the most serious food safety risks.

Any changes in the meat inspection system must also be made within the context of the entire food safety system. In this regard, we reported in June of 1992 that this entire system needs to be fundamentally restructured. We believe that ensuring the safety of all foods would best be accomplished by a single consolidated food safety agency and recommended forming a blue ribbon panel to study the feasibility of this and other approaches to strengthening food inspection.

My prepared testimony makes several recommendations relevant to the issues I just described, including developing an operational plan, working with all interested parties to build a consensus, and seeking needed legislative changes and obtaining congressional guidance on the objectives of the meat and poultry inspection system.

That concludes my summary, Mr. Chairman. Mr. Zadjura, who I failed to acknowledge at the beginning of my testimony, is also with me. He is assistant director responsible for our work in the food safety area.

[The prepared statement of Mr. Harman appears at the conclusion of the hearing.]

Mr. STENHOLM. Do you have any comments, Mr. Zadjura?

Mr. ZADJURA. No.

Mr. STENHOLM. We thank you all very much for testifying this morning and giving us a lot of good sound fundamental information to build on. And certainly, Mr. Harman, I could not agree more with your last statement that you made in which this system needs to be fundamentally restructured. That is exactly what Dr. Cross suggested in his opening statement and CDC in their own way confirmed the same general observation.

It is something that has been particularly frustrating to me over these last several years as we have tried to do just that and have been frustrated often by the loudest critics of the system. Even as we have tried to move forward with meaningful changes. Some critics have claimed that we were standing in the way of progress. But enough of the past, what we are looking for now is the future.

Dr. Hughes, in your statement you say we have learned a great deal about foodborne disease in the last 15 years. Are there any trends along these 15 years? Is there anything that you have discovered as you look at what has occurred in foodborne diseases during these 15 years that you would be able to share with us today?

Dr. HUGHES. Yes, let me make a couple of comments in response. It is interesting that 19 years ago I joined the CDC and began to work on foodborne disease full time. The nature of foodborne disease today is dramatically different than it was when I first arrived at CDC.

We have identified new foodborne pathogens, as I mentioned in my testimony: *E. coli* 0157:H7, that has been mentioned a number of times, is certainly one. *Campylobacter jejuni* is another. We have *Listeria monocytogenes,* which produces meningitis, is a third. This was a recognized disease when I arrived at CDC but was not suspected by anyone at that time to be foodborne.

So I think our experience teaches us that we will continue to encounter new microbes that are transmitted by food, and we will probably learn in the future that other infectious diseases not currently recognized to be foodborne are transmitted by food under certain circumstances.

I wish I could say more about trends in foodborne disease outbreaks. I will make a comment and maybe Dr. Cohen could elaborate a bit. The national surveillance of foodborne disease outbreaks, as I indicated, is based on efforts of State and local health departments who these days are pulled in many directions by competing priorities. The number of foodborne disease outbreaks that we have heard about over time is, in part, related to the priority and attention that State and local health departments can devote to investigating reports of such outbreaks.

So the trends have fluctuated some over time based on that level of effort. I believe that it is important that we continue to acknowledge the critical importance of national surveillance of foodborne disease outbreaks as we move forward with making changes in the existing regulatory approach.

Mr. STENHOLM. Dr. Cross, your suggestion for your track I and track II approach that you are talking about now, does FSIS have the authority to carry out track I and track II without legislative assistance?

Mr. CROSS. Mr. Chairman, I think we have the authority to do almost all that we plan to do on track I, but I doubt very much if we have the authority that we are going to need to do when we decide what track II is going to be.

I am not being facetious when I tell you we don't know what it is going to be because we have not designed it yet. So I would say we would very much need your support as we move into track II.

But track I, as we moved into this over the next few weeks and months, we will identify any authority that we need, but at this point I think we have most of what we need.

Mr. STENHOLM. Again, Dr. Cross, what is your zero tolerance policy for ingesta, feces, and milk; and is this a new policy?

Mr. CROSS. No, Mr. Chairman, it is not a new policy. We have had a policy for years on the books for zero fecal ingesta. What we are doing today, what we started doing a few weeks ago, is to make sure our inspectors in the field know this is our policy and know that they have the authority to remove this contaminant at any time.

We have also changed the location in the process as to where we are going to insist this be removed. In fact, in meat plants, beef plants in particular, we are going to insist it be removed prior to washing, prior to going into the cooler. So it is definitely not a new policy.

Mr. STENHOLM. I will have some additional questions later. I want to recognize the presence of the chairman of the full committee, Mr. de la Garza is with us.

Mr. Chairman, would you have something to say.

The CHAIRMAN. Thank you, very much, Mr. Chairman, and I commend you for having this hearing. It is a very timely, and I hope this is the beginning of getting on with the solution to the basic problem.

I just have a couple of short questions. One, I have been saying we have the safest food in the world of the major industrialized countries in the world. Am I wrong or am I right?

Mr. CROSS. Mr. Chairman, you are correct. I will say the same thing, and many others say the same thing. What I am saying today is we have the safest meat and poultry supply in the world but that does not mean we cannot make it safer, that does not mean we cannot improve the current inspection system to make it safer.

The CHAIRMAN. Very good. That was my next question. You anticipated it. Have any of you, gentlemen, had an opportunity to visit the inspection systems in other countries that you can relate to how we do it?

Mr. CROSS. Yes, sir. We spend quite a lot of time in looking at other countries' inspection systems, particularly those countries that export product to this country, because our current international program inspection system is set up such that in order to export to this country, you have to have an inspection system equivalent to the one in this country.

Most recent, we spent an awful lot of time looking at both Canada and Mexico, and their inspection systems particularly in relation to NAFTA, and we are quite pleased with what we are finding, but the answer to your question is, yes, we have looked at many countries around the world. We are always willing to learn, if they have a better way, we will use that better way. But the communication with countries we do business with is very extensive.

The CHAIRMAN. And you have shut down some plants in several countries that may get below the standard that we insist they have. Is this correct?

Mr. CROSS. Absolutely. That is a very routine occurrence, Mr. Chairman. We do that on a very, very frequent basis around the world.

The CHAIRMAN. Now, recently, one of my colleagues, who chairs a subcommittee on another committee, made a statement that beef had come through Canada and that this may have caused what happened in Washington State, or there may have been an illicit transshipment of beef from Canada to the United States. Do you know anything about that?

Mr. CROSS. Yes, we do, Mr. Chairman. We did have a situation early this year in which seven loads of Australian beef came through Canada and it was not identified on the health certificate as coming from Australia, but the boxes were labeled Australian meat. This was a market quota issue and not a public health issue.

The meat was inspected in Australia. It was inspected when it entered Canada. It was inspected again when it entered our country. And so we have corrected that error to make certain it does

not happen again, but I do want to emphasize that was not a public health error, that was a marketing error, and we have also looked very closely, during the *E. coli* outbreak, at the suppliers of meat to the company in California that was implicated in the outbreak, and we have no reason to believe that this was at all linked to products coming in from other countries.

The CHAIRMAN. Now, could we have a food chain inspection system? Here we are talking about meat. Can we follow meat from the cow in the pen out there at a ranch all the way to the slaughterhouse to the wholesaler to the retailer to someone's kitchen, either at home or in a restaurant?

Mr. CROSS. Mr. Chairman, basically, I think what we are proposing in the future is a farm-to-table system, but we are not proposing the Government do it all. We are proposing that the industry have a key role, particularly on the farm. We are also proposing that we do go back to the farm ourselves and trace back sources of pathogens and chemicals.

We are proposing that we have an intensive role through slaughter, processing, and some points through marketing. We are proposing that FDA and other State and local authorities have a key role about what happens at retail food service and consumers also have a major role in food safety. We cannot go into their homes and cook the meat for them or tell them how to cook the meat.

The CHAIRMAN. That would be an education of sorts.

Mr. CROSS. Very strongly.

The CHAIRMAN. We keep hearing there are not enough inspectors. I have a friend who has a small slaughterhouse and his complaint is they are over him all the time. They have nothing to do. They police the grounds and there were too many papers laying around. He is on the side of a highway, and paper trash was getting caught against his chain link fence, and they wrote him up for that or something.

Mr. CROSS. Well, basically, we do have a shortage of inspectors, but we do have isolated examples that you just described, Mr. Chairman, and we deal with those when they are made known to us. But basically we are operating under statutes that require bird by bird, carcass by carcass, inspection, and over the last 5 years we have been stagnant in terms of hiring; in fact, we have gone down in inspector numbers when the industry has actually been growing. And the law does require us to provide inspection if requested by industry. It has caused us to do some things that may be a little uncomfortable.

The CHAIRMAN. My time is about up. But I can keep on saying that we have the safest, we have the best food inspection system in the world. We have the safest food in the world, but it does not mean we cannot make it better. Is that it?

Mr. CROSS. Absolutely.

The CHAIRMAN. Thank you, very much, Mr. Chairman.

Mr. STENHOLM. Mr. Smith.

Mr. SMITH. Thank you, Mr. Chairman.

Dr. Hughes, a hypothetical. If that hamburger in Washington State were cooked at 155 degrees Fahrenheit for a specific amount of time, rather than less than that, would the same horrible occurrence have occurred?

Dr. HUGHES. I think it is quite likely that had those hamburgers been cooked to the point where they were no longer pink, that the outbreak would not have occurred.

Mr. SMITH. So, then, I want to ask you a general question. In the area of food preparation and handling, how many of these pathogens and bacteria could we take care of by improving handling and cooking?

Dr. HUGHES. I think that, as has been alluded to by Dr. Cross already, that food preparation and handling practices are critically important in addressing.

Mr. SMITH. I know they are critically important. I am asking you to give me an estimate of the 80 million people who have had food-related sicknesses, how many of those could be eradicated by proper handling and by proper food preparation?

Dr. HUGHES. I cannot give you a precise estimate.

Mr. SMITH. Of course not.

Dr. HUGHES. I think the number of cases could be substantially reduced by improved handling practices.

Mr. SMITH. Over half?

Dr. HUGHES. Maybe half.

Mr. SMITH. So it seems to me, Dr. Cross, that when we try to take care of this situation, knowing that there are 7 billion animals slaughtered every year, the addition of 160 people, is that a make-me-feel-good program? Should we have 5,000 more people, or should we have any, or are we misdirecting the effort, since it is estimated—let's take over half of the related health problems come from handling and food preparation, and that situation would not have occurred in Washington had those hamburgers been prepared at 155 degrees Fahrenheit. Then we should have a massive education program rather than adding more inspectors.

I am assuming your premise, but I would like your answer.

Mr. CROSS. Congressman, I don't feel that we can put all the burden and all the responsibility for safety on the public or the consumer, although a significant amount of it is going to be there. And so we strongly believe and strongly support the increased communication and education awareness at that level.

In regard to the other 160 inspectors we hopefully will get this year and perhaps next year, these inspectors will not solve all our problems. These inspectors are not new. These inspectors are needed to do the tasks that have been undone for a number of months or years. These inspectors are not going to make the product pathogen-free. The kind of things we have outlined in our pathogen strategy are going to accomplish that, not pathogen-free meat and poultry, but major pathogen reduction.

So as I mentioned in my testimony, these inspectors are needed to do many other tasks that are left undone right now, some tasks that are related to public health and some are related to economic adulteration.

As we look at the inspection of the future, we will have to see where we need these people and what kind of people we need. I can see down the road a tremendous amount of microbial monitoring and these people will have to be trained to do these kinds of tasks.

Mr. SMITH. In your track II program, tell me, you say you will develop that without budget or legal restraints. Then it seems to

me we are placed in a situation, if you do that, I can do that myself. I can suggest to you that we have 7 billion animals slaughtered every year; we need 7 billion people so that we inspect every one of them, or the equivalent. I can give you an inspection program without budget or legal restraints that will get us to almost a zero tolerance factor, but then are we not faced with the question we either enact a draconian system without budget control, or we have spurned food safety. Then we have no choice, we either say sorry, we are not going to protect food, or we spend $300 billion for food safety?

Mr. CROSS. Congressman, I didn't mean to imply we would just totally ignore resource requirements because that is impossible in any environment. But I did not want to restrict the thinking of the people that put this plan together based on current meat and poultry statutes or current thinking with regard to the kinds of things that we are doing today. I wanted them to start from scratch. I wanted them to be able to say what is the best system in the world, then we will put the dollars and cents to it and see if we can, in fact, get it done.

Mr. SMITH. Dr. Hughes, very quickly, I don't know what 155 degrees Fahrenheit for 13 seconds in the middle of a hamburger means. Should I ever eat a raw hamburger again, or how about a medium rare one, or a medium one, or a well done one? In my language, what should I do?

Dr. HUGHES. We say cook the pink out. Don't eat pink hamburger.

Mr. SMITH. Is that a medium to me or how do you do that?

Dr. HUGHES. To me, that would be medium. But I think to all of us, the key is to ensure it is not pink when you eat it. I have changed my eating habits, I must say.

Mr. SMITH. Just quickly, in meat, hamburger, I understand, is the carrier because it is an inside-outside meat, more so than steak, roast, just quickly tell me about that.

Dr. HUGHES. That is true. When the meat is ground, surface contaminants can be well mixed through the meat and, therefore, it becomes crucial to cook them thoroughly throughout in order to kill the microbes.

Mr. SMITH. It is the most dangerous carrier of the meat roughly, hamburger is the most dangerous if it is not cooked properly?

Dr. HUGHES. If it is not cooked properly, yes, sir.

Mr. SMITH. Thank you.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. First, I want to congratulate Dr. Cross, especially on the pathogen reduction program, and I would like to ask a little bit about that, because we want to get to the bottom of trying to at least reduce the opportunity for bacteria or the microbial disease.

Is there any way to assess the risk of the various types of microbial organisms that would be in the meat supply from the time it is on the farm, then it gets into the slaughterhouse, and as it is being slaughtered and then being cut up or frozen or whatever, and through that packing plant and what occurs there, and then through the various stages after that as it is cut up and boxed or shipped out and then is retailed and all those things?

Is there any way we can assess the risk of the various types of microbial organisms as to what stages that might occur?

Mr. CROSS. Mr. Chairman, the answer to your question is, yes, eventually that can be done. That is what we call quantitative risk assessment and it will have to be done probably by organizations like CDC, but much of that data is not available and it will take many years to collect it.

We are talking about dose response data. We are talking about data for different types of populations in this country, some more susceptible than others. I don't think we can wait that long to be able to take action. So our strategy on the pathogen reduction is we think, yes, that data is needed and we will support whatever governmental agency wants to collect that data, and my guess would be the fellow to my right here.

But first we have to reduce the pathogen levels. We cannot tell you what a safe level is or whether it is 1 or 10 organisms or 1 million organisms that will make the individual sick. Our goal is to get the numbers down as low as possible as soon as possible.

Mr. VOLKMER. I notice in your testimony that we can do some things by perhaps limiting the way we slaughter, the way we handle, the way the equipment is in the packinghouse, what happens back on the farm, all these things can be done in the meantime; can they not?

Mr. CROSS. Absolutely, Mr. Chairman. When we use the term HACCP a lot; that is, hazard analysis critical control points, you identify all the points in the raising of the animal, the slaughtering of the animal, the processing of the animal, the marketing and distribution of those products. You identify all the critical control points and see if they are out of control and allowing pathogens to grow.

What we are trying to do with our pathogen strategy is to evaluate those critical control points for pathogens. We will know when the process is out of control. We will have to take regulatory action to get the process back under control. That is our best strategy to reduce pathogens.

We think that if we can put the industry on a microbial footing over the next few months and years, if we can have the industry do a lot of their own microbial sampling and have us evaluate their data, we can go very far toward reducing pathogens.

Mr. VOLKMER. Dr. Hughes, do you have any comment on those questions?

Dr. HUGHES. I think we can learn a good bit from outbreak investigations that we do about necessary information in terms of critical control points and we can learn exactly where it is in the chain that something went wrong that caused the outbreak to occur.

I would like to make one other point, and that is, given that we are going to be, it seems, making some changes in the way we do business, I would just like to say I think it is critically important that we maintain and even enhance foodborne disease surveillance in this country so that we are able to evaluate the impact of changes that are made.

Mr. VOLKMER. We already know do we not, Dr. Cross, and perhaps, Dr. Hughes, we already know that in certain types of meats,

in other words in raw, you are more apt to have *Salmonella* than in others; is that correct?

Mr. CROSS. Yes, that is correct.

Mr. VOLKMER. We can do things, can we not, in the processing chains, to reduce, not necessarily eliminate, but reduce the opportunity for that *Salmonella* to end up in my tummy; correct?

Mr. CROSS. Absolutely, Mr. Chairman. Those are what we call intervention or prevention-type systems. A good example would be organic acid rinses, which are effective on some pathogens; trisodium phosphate, which we approved for the poultry industry last year; and irradiation, which we approved for poultry.

Those are excellent examples of prevention systems that can stop the growth of pathogens or reduce the growth of pathogens at key points along the chain.

Mr. VOLKMER. My time is about up, but I have one more question for anybody on this panel who wants to answer it, and that is something that occurred to yours truly back about 16, 17 years ago, and because of an acute stomach, tummy ache and lower intestines, and I had to actually get a doctor in and I thought I was going to the hospital it was so bad. But after I told the doctor what I had had to eat that day and everything, he told me that in his opinion what I had was an acute case of *Salmonella* poisoning. But that I had probably gotten it from a person who handled my food that day for lunch. And after I described to him the lunch, not from the lunch itself.

Is it possible that I can be contaminated by the person who either prepares that food or serves that food, Dr. Hughes?

Dr. HUGHES. Yes, that is possible, and the likelihood that that would occur will vary among the foodborne pathogens tremendously.

Mr. VOLKMER. Tell me how it occurs. I didn't have time to talk to the doctor, I was so miserable. I could have cared less at the time. I have always wondered about that, and that bothers me, here we are going through this process and doing all these things and spending these millions of dollars to make food safe and somebody down at the deli for some reason or other is able to transmit it to me because that person has it.

Dr. HUGHES. Well, an infected food handler who handles food, if their hands are contaminated with feces and they are, say, infected with hepatitis, *E. coli*, or, occasionally, with *Salmonella*, they can contaminate the food, and they contaminate it up to a certain point and you ingest it, then you can acquire foodborne disease that way.

Mr. VOLKMER. So what do we do about that?

Dr. HUGHES. States and local health departments, particularly, put a lot of time and effort into monitoring food handling practices in food service establishments. It is critically important that food handlers who have similar symptoms of infectious diseases that might be transmitted by food not work while they are ill or while they are recovering.

Mr. HARMAN. Mr. Chairman, that is precisely why the type of system that Dr. Cross is advocating is needed, the HACCP-type system to identify those things. It is very good to have the whole system work and then at the end someone—it breaks down, it

doesn't do you any good, and that is why we need that type of system he is advocating.

Mr. VOLKMER. Thank you very much. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Gunderson.

Mr. GUNDERSON. Thank you, Mr. Chairman.

I have had a chance to review your entire testimony, Dr. Cross, and I don't know that there is any question about all of us having the same goal. I think there may be some question about the tactics we use to achieve that goal.

Is it a fair statement to say that there is a consensus regarding the Washington outbreak of *E. coli* that the problem or the failure there and the breakdown of the system was not a result of meat inspection but rather in the preparation of the finished meat product? Is there a consensus or not?

Mr. CROSS. Within our shop, Congressman, it is a consensus. We feel the inspection system, as it is designed and is functioning today, functioned properly.

Mr. GUNDERSON. I think that is important, because then we are also talking about the fact that the real problem today is that there have been no advances, very frankly, in the technological aspects of the inspection system. Is that correct?

Mr. CROSS. No, we would not agree with that.

Mr. GUNDERSON. You wouldn't.

Mr. CROSS. No, we think we have made significant advances, particularly on the chemical residue side. We have made significant advances on the rapid method development for some of the key pathogens. And so we have made advances, not nearly rapid enough, and we have not implemented some of the risk-based inspection principles we need to. But I would not say we have been standing still.

Mr. GUNDERSON. How about in the microbial detection side?

Mr. CROSS. We have made significant advances, not nearly as much as we have on chemical residues. Of course, chemical residues are much easier to do. But over the last probably 7 to 8 years we have had significant advances getting up to almost a 24-hour test on some of the pathogens. So we have made advances, yes.

Mr. GUNDERSON. The problem I have with this whole discussion since the *E. coli* breakdown is, why are we taking $4 million of limited Federal money and spending it on 160 to 270 new meat inspectors to make us feel good, when what we really need to do is spend that money, as you indicate very frankly, on an accelerated timetable to deal with the aspects of technological research in the whole inspection system?

Mr. CROSS. First, I would say they are not new inspectors. They are inspectors to replace vacancies we have had for a number of years. What we have had to do, as an agency, Congressman, is primarily because the law requires us to look at every bird and every carcass. The law requires us to respond to a growing industry, so that when they want to add second shifts or new plants, we have had to move processing inspectors over to the slaughter line in order to accommodate those statutes.

In doing that, we have done some things that worry me greatly. Basically, instead of having an inspector in a plant every day at

every shift, I have some inspectors looking at 12 plants a day. That worries me greatly.

Our PBIS, our performance-based inspection system, prioritizes those tasks for that inspector, based on public health significance, but we have stretched ourselves as thin as we can stretch with the 550 vacancies we have. We are asking our inspectors to do double and triple shifts to make ends meet.

So I am not saying these 160 inspectors will address the pathogen strategy; I am saying the 160 inspectors will address a critical need that has been facing this agency for about 5 years.

Mr. GUNDERSON. Let's assume that we totally accept the thesis of PBIS. Do 160 new inspectors bring you up to 100 percent capacity in inspection?

Mr. CROSS. No.

Mr. GUNDERSON. What would?

Mr. CROSS. 500.

Mr. GUNDERSON. 500. Then why 160? I don't understand where 160 came from.

Mr. CROSS. I don't know where it came from either. That is not the number we presented. We will take anything we can get, Congressman. We have been looking for new inspectors—not new inspectors, but to fill these vacancies we have had for many years, and so if you give us one, we will take it; if you give us 500, we will take that, too.

Mr. GUNDERSON. So if 160 costs $4 million, 500 would cost roughly $15 million. So you requested $15 million for additional inspectors, but OMB said no, so you are not going to ask for that much?

Mr. CROSS. Basically, what we also told the Secretary—he asked us what we could effectively hire and put on the books the remainder of this fiscal year, and I think that is where the 160 came from. We can only hire so many people and train so many people during a given time period; therefore, the 160.

Mr. GUNDERSON. But my confusion in the budget that is in front of us and the request that includes this $4 million is, all right, you have 160; you wanted more, but this is all you could get.

What do you have in terms of funding for the accelerated timetables of your testimony here regarding both the microbial and the rapid detection system? What kind of request have you got for money on this side, where there is what I think is a universal consensus of where we need it?

Mr. CROSS. I don't feel comfortable, Congressman, discussing the dollars for 1994, since we have not seen the President's budget yet. Now, I have some figures within the agency as to what I think it will cost to get the job done. Whether that will be in our budget, we don't know yet, for 1994.

Mr. GUNDERSON. So as of today, we have no request from USDA for more money for an accelerated timetable on the technology side?

Mr. CROSS. I am sure that is going up through the channels on the budget request, yes.

Mr. GUNDERSON. But we don't have any in the stimulus package?

Mr. CROSS. No.

Mr. GUNDERSON. But we have $4 million. Wouldn't we be better splitting the $4 million and putting half of that toward accelerated research?

Mr. CROSS. We don't think so. In other words, I feel so strongly about the critical need of these vacancies and how far we have stretched ourselves that I could not justify not requesting these vacancies.

I will say, Congressman, that I have identified approximately $600,000 within the agency that I will move from activities that are lesser priorities to the pathogen strategy so we can begin the strategy this year.

Mr. GUNDERSON. Let's assume you cannot give it to me until the end of the month when the budget comes up here, and I respect that constraint on your time. Could you submit to these two subcommittees the timetable and the budget plan that is the foundation for achieving the rapid detection system that you are advocating?

Mr. CROSS. Yes.

Mr. GUNDERSON. So that we know exactly that you will have 160 inspectors, you will have x amount in this research and y amount in this kind; and we will see a timetable going over the next 5 years, going from 160 to 550 new inspectors, and x to x-plus in terms of research, so that we can see the entirety of the plan?

Mr. CROSS. Absolutely.

Mr. GUNDERSON. I appreciate that very much. Thank you.

Thank you, Mr. Chairman.

Mr. STENHOLM.

Mr. HOLDEN. No questions, Mr. Chairman.

Mr. STENHOLM. Mrs. Clayton?

Mrs. CLAYTON. Thank you, Mr. Chairman for having this hearing, and I also thank the panel for their remarks and some very candid remarks.

I wanted to comment that, Mr. Cross, I appreciate your proposal of what you plan to do, but apparently, Dr. Doyle did not agree with that. Would you comment on that?

Apparently, you were under the impression that just to expand this plan, you felt, was inadequate and would not be the appropriate way to correct what you found was a bad plan. Can you comment further on your comments of Mr. Cross' plan to improve?

Mr. HARMAN. Are you referring to me?

Mrs. CLAYTON. Yes.

Mr. HARMAN. I am John Harman.

Mrs. CLAYTON. I am sorry, Mr. Harman.

Mr. HARMAN. That is OK.

Well, in theory we agree with the approach that FSIS is going with. It is an approach we have advocated for some time. The problem, really, is how do you achieve this change? There seems to be a real consensus; you can sit around this room and hear people say that the threat has changed, the threat is not the same threat as we had 20, 30, 40, 50 years ago, but the inspection system has not changed.

I have a lot of doubts personally about adding additional inspectors and what that is going to give us in terms of the trade-offs that we could use to start to move toward a different kind of sys-

tem. This is not going to be an easy process. There are a lot of people that view themselves as having something to lose, and when you have that kind of situation—and usually that is a situation you always have when you have change—there are going to be some real problems.

So the key here is going to be, how do you bring all these different people and different groups, consumer groups, inspector groups, into this process. And Congress, as I said, has a real key role to play here; because I think we have been talking about, to some extent, these changes since 1977.

There was legislation passed in the 1980's to try to make some changes that did not occur, and the reason it did not occur, in our view, is largely because the process was not there to make it occur; and Congress has a real key role in the partnering process.

But, basically, in terms of creating a science-based, risk-based system, we agree with the direction FSIS is going in. Right now it is all, for the most part, proposals.

Mrs. CLAYTON. Either of you, would you just comment, what are the objectives of the science-based meat and poultry inspection program? What would be the objective of that science-based inspection program?

Mr. HARMAN. The objective of the science-based program would be, obviously, to improve; and the ultimate objective would get to where there is no risk. But that is obviously not going to be the case.

What we need to do is identify, as someone pointed out earlier, those processes, those areas, where the most risk exists; and then bring to bear any kind of improvements in microbial testing or the kind of testing that needs to be done to those processes. We don't need to take tests of every individual piece of meat, or every individual chicken.

First of all, I think poultry is in a state that most people know that there is a problem with *Salmonella* in poultry, and you have to cook it. Some of the problem comes in the handling of the poultry, but that is a key process there, that consumer education. But there are a lot of processes in between, and we would advocate a system where you identify those risk areas, those areas of highest risk, and then you go after those areas—not only areas in the process, but perhaps processors also, those processors that are having the most problems, and go after those processors and put more of your resources on those rather than having inspectors at every plant, every day, that cannot get at the kind of problem we are talking about right here, right now.

Mr. ZADJURA. Can I add maybe an example or two that I think will get to the point?

Our system is not very scientific; it is based on looking at an animal or carcass to see if there is a tumor a cyst or dirt. Inspectors go in the plant in the morning and do essentially a military, white-glove inspection. If the table looks clean, it is clean.

We know of at least one plant that went out and started doing their own microbial testing and found out equipment looks clean, but it was highly contaminated and carried potentially harmful microbes; so they changed their system. Yet the Federal Government was coming in there every day and saying, it looks clean, it is good.

It is not scientific; it is not based on risk.

The risk of some operations is very low, yet we inspect them every day. It is also based on the law. If the local grocery store cuts up chickens into chicken parts in the back room, it does not come under Federal jurisdiction because it is a retailer and comes under local. If they do it at a central facility, then FSIS sends an inspector in there every day.

I would contend there is no difference in the risk, but yet in one case we get an inspector every day and in the other we don't get any.

Canning operations, if they are canning a product that has meat or poultry in it, FSIS is in there every day. We know of at least one plant that has 17 FSIS inspectors. If the next day they make vegetable soup, it is under FDA's jurisdiction, essentially, because FSIS only has meat and poultry. FDA comes around once every 3 or 5 years.

Now, either this plant needs to be inspected every day, because it is risky, or it needs it once every 3 to 5 years.

The basic fact of the matter is, the real risk is not meat or poultry, which by that time has been inspected many times from slaughter to processing by the Federal Government. The real risk system there is that it is a canning operation. And our contention is the inspection should be based on the fact it is a canning operation, and a canning operation poses a certain level of risk, not that we have a law that says because it has meat in it, it has to be inspected every day or continuously.

Mr. CROSS. If I could comment?

Mrs. CLAYTON. Yes, Mr. Cross.

Mr. CROSS. Chairman de la Garza is right, and I agreed a few minutes ago, we still have the safest meat and poultry supply in the world, but it can be made safer. We didn't get to where we are today by not doing some things right.

Organoleptic inspection is talked about a lot and the fact we need to move away from it. Organoleptic inspection still involves looking for indications of disease, and that still needs to happen. It also involves looking for fecal contaminants; that still needs to happen.

We also need to make sure we don't have chemical contaminants in our meat and poultry supply. We have had great success in that over the last decade. That does not need to go away.

There is no question that the inspection system of the future needs to be based on risk. We need to define what that risk is, and right now we do a lot of risk analysis in our inspection system, but that is based on qualitative risk judgment, not quantitative. And so as we move to the inspection system of the future, we don't know if we need 17 inspectors or 7,000, but basically our risk tells us we need to be there.

Some of our laws say we need to be there. All this needs to be looked at as we look at the track II, the modernization of inspection, and as we look to the future. But because we are going to do that over the next 2 or 3 years, we cannot just stop what we are doing now and lose more consumer confidence in our meat and poultry safety practices. We have to continue. We cannot have

those inspectors in those plants today, we may not have them tomorrow, but we cannot change it overnight.

Mrs. CLAYTON. Mr. Chairman, just one more question.

Mr. Cross, would you agree with the National Cannery Science Report and with their definition of what is a science-based requirement for meat inspection?

Mr. CROSS. Yes, ma'am. We paid for those studies, and we have used a great deal from those studies. I will have to admit we have not used as much as we will, but they recommended a strong risk-based, science-based inspection system. We agree with that.

Mrs. CLAYTON. Are you following that?

Mr. CROSS. We are following a significant number, but what we have found, and what I learned in looking back over the last year, is that trying to use the evolutionary approach, trying to implement things one step at a time in our present inspection system has not worked as effectively as it should have.

Our critics came out of the woodwork and hammered us many times as we tried to take some steps in different directions. So I feel we need to do the future-based system of track II; we need to take the good parts of the Academy recommendations and move forward aggressively with strong political support, strong scientific support, and move forward in one giant step.

Mrs. CLAYTON. Dr. Hughes, are you convinced that the Agriculture Department can prevent this as much as they indicate they can?

Dr. HUGHES. I think the prevention strategy is multifaceted and involves actions at different levels. I think the Department of Agriculture has an extremely important contribution to make. But as we have talked about earlier, in the end, there are others involved, including those who prepare food. So an overall foodborne disease prevention strategy is truly multifaceted.

Mrs. CLAYTON. Thank you, Mr. Chairman.

Mr. HARMAN. Mr. Chairman, could I just add one thing in response to what Dr. Cross said. We in no way are advocating you just use microbial testing as the only means of an inspection system. Obviously, you still need the type of things he mentioned. You need all the tools. You have to have all of them.

Mr. STENHOLM. Mr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman. I have a question for Dr. Cross.

You mentioned in your testimony that research data from universities will be an important aspect of your research program to reduce the level of foodborne pathogens. How do you envision information from that part of the program—well, how do you envision implementing that part of the program dealing with university research?

Mr. CROSS. Well, basically, Congressman, when we say that we need data to support programs, normally what we do—either through the Agricultural Research Service or directly through the universities—we tell them the kind of questions we need answers to. The funding for that research is many times provided by the taxpayer, many times it is provided by the industry. But we have very close communications with our universities, we have very close communications with our sister agencies that do the research.

In fact, we are having a meeting today in Beltsville with all of the USDA agencies involved in research to prioritize research issues for our pathogen strategy.

Mr. ALLARD. My understanding is that you are looking at setting up some red meat research centers where you would be looking at better ways to process information and do additional research on red meat, particularly?

Mr. CROSS. Congressman, I believe the farm bill does provide for the establishment of four safety-quality centers, and I don't believe those have been established yet.

My personal opinion is if a university is willing to dedicate its resources to have such a center established, that is to our advantage, because that means they are also going to dedicate some of their State dollars to that area.

So if somebody comes to us and says, yes, we want to be a safety center, that is great, we support that, because that means we can leverage our Federal dollars. But I also need to go further and say when we spend Federal dollars for research with the State universities, we like to do that in a very strong, competitive mode. We put the project out for bid and we take the best proposal and fund it.

Mr. ALLARD. You are going to try to designate some regional centers of excellence and go with them; is that what your plan is?

Mr. CROSS. FSIS will not be doing that, but it is very likely that the Secretary could be doing that.

Mr. ALLARD. I see. Thank you.

The other thing, on your pathogen reduction program, do you plan on including industry participation in putting that program together, or have you already done that?

Mr. CROSS. Yes, sir; we do. Yesterday I got the final go-ahead from the Secretary to begin discussing the pathogen strategy with all of our constituents, which includes industry, the consumer advocate groups, and of course, the public and the research community.

But as I mentioned earlier, this plan we are advocating is a farm-to-table plan that involves key participation with industry and the consumer. A good example would be how industry performed in working with regulatory agencies to control the violative residues of chemicals in meat and poultry.

The programs that have been implemented in well over 40 States by industry have played a significant role in the reduction of violations from 1979 to the present time, in which we have less than three-tenths of 1 percent residue violation rate.

Mr. ALLARD. What plans does the agency have for preharvest—and in my way of thinking, that is on-farm investigations of food animal carriers of pathogens and of management practices to prevent introduction of these pathogens into the food chain?

Mr. CROSS. The first word that comes to mind is research. There is so much that we don't know about what is going on preharvest. And so we have identified in our priorities, working with our sister agency, APHIS, a series of research priorities that have to be funded and conducted.

Our long-term or intermediate-term goal is to develop a HACCP program on the farm; look at certified flocks, herds, perhaps even change the way we inspect animals that have been identified as

being free of pathogens; develop vaccines to inhibit the growth of some of the key pathogens; and to look at irradiation of feed.

But before we get to those intervention steps, we have to learn a lot more about the ecology of pathogens in the live animal, particularly the healthy animals, which we cannot detect using present-day technology.

Mr. ALLARD. Are you thinking of any on-farm testing procedures or epidemiological techniques that you would be implementing?

Mr. CROSS. Eventually, yes, we would love to; if we can get the right kind of information in our research and get the answers we need, we would love to have those types of systems available to us for implementation.

Mr. ALLARD. What type of on-farm testing procedures are you thinking about?

Mr. CROSS. We are thinking about rapid tests for key pathogens, so we could detect the presence of pathogens, either a fecal test or urine test or a blood test.

Mr. ALLARD. Thank you.

Mr. STENHOLM. Mr. Peterson.

Mr. PETERSON. Thank you, Mr. Chairman.

Dr. Cross, I apologize for being late, but I have read over your testimony a little bit, and in looking at it, it appears that you believe that there needs to be some risk assessment developed in this track II, so you can get to a science-based inspection system; is that a fair statement?

Mr. CROSS. Yes, sir; very much.

Mr. PETERSON. Evidently, you have only been on the job what, 18 months?

Mr. CROSS. Thirteen months. Seems like 18 though.

Mr. PETERSON. But, evidently, these recommendations came about in the middle 1980's, is that correct, that the Department or that you move in this direction?

Mr. CROSS. Yes, sir, the National Academy of Sciences' recommendations came from the 1985 and 1987 study. And I don't want to give the subcommittees the impression we have not implemented a significant number of these recommendations. So, yes, they did.

Mr. PETERSON. But it took until 1992 before you actually set up a task force to really focus on this; is that correct?

Mr. CROSS. No, not totally correct. We have had many task forces that have been established, and as soon as I came on board in 1992, the staff showed me the direction that they would prefer to head. I agreed with most of it; some I didn't, and so I wanted to make sure when I finished 1992 I had a direction firmly established in my mind as to where this agency is going to head.

Mr. PETERSON. Now, how does this task force operate? Does it have some full-time people that work just on this?

Mr. CROSS. Basically, on the pathogen strategy—is that the one you are referring to?

Mr. PETERSON. Well, getting to a risk-based system. As I understand it, that is what this task force is supposed to do, is lay out the plan of how you are to get to this new inspection system.

Mr. CROSS. Let me clarify. We are talking track I and track II. Within track I is the pathogen strategy that we have been talking about today.

Mr. PETERSON. I am not talking about that.

Mr. CROSS. You are talking about track II, the future system?

Mr. PETERSON. Right.

Mr. CROSS. That is in the midst of being designed for presentation to the Secretary. At this point, we know that FSIS alone cannot design the inspection system of the future. We would prefer not to. We would prefer to get input, definitely, from outside our agency, perhaps even outside Government.

So in the next few weeks we will make a recommendation to the Secretary as to how we would propose that he proceed in developing a track II strategy and implementation.

Mr. PETERSON. Do you have full-time people working on this in your agency?

Mr. CROSS. Yes, we have 10 or 12 full-time staffers working on this now.

Mr. PETERSON. And there is some talk about there being some kind of summit; is that involved in this?

Mr. CROSS. That is a potential thought that we are contemplating.

Mr. PETERSON. That might be something that will come out of this.

Mr. CROSS. Something like a food safety summit, that the Secretary could host.

We also have another meeting scheduled that is held every 4 years in a different country, to which we will invite 30 people, key inspection people, from 30 countries to sit down with us in October to discuss the modernization of meat inspection, meat and poultry inspection, worldwide. Mainly this is to get their input on things like risk analysis, HACCP, et cetera.

Mr. PETERSON. So this is on the fast track?

Mr. CROSS. That is on the books. The invitations have already been issued to the 30 countries.

Mr. PETERSON. And the Department is going to—your agency will be the lead on this?

Mr. CROSS. Yes.

This is designed, Congressman, to be part of track II. It is coincidentally going to be occurring. This is a meeting held every 4 years in a different country, and it just happened to be our turn to host this meeting; and so we changed the focus of the meeting to coincide with what we would like to do in regard to track II.

Mr. PETERSON. So, as I understand it, when Secretary Espy was over at the Senate he was talking about this summit?

Mr. CROSS. Yes, he may have mentioned it.

Mr. PETERSON. This includes all these other countries?

Mr. CROSS. Yes.

Mr. PETERSON. This is not something specifically designed to deal with our problem here?

Mr. CROSS. No, it is not. In fact, it could very well be that the Secretary could decide at some future point to have his own summit for safety and make it across all food, not just meat and poultry.

Mr. PETERSON. Is that something under consideration?

Mr. CROSS. It is being talked about, but is very preliminary at this stage.

Mr. PETERSON. I have had people visiting with me who say there is some concern that if we do get into some kind of a situation like that, that we consider having a third party host this, because there is some, I don't know what you want to call it, but——

Mr. CROSS. Bias.

Mr. PETERSON. I guess there has not been the greatest relationship over the years amongst some of the different groups involved in this, and they are concerned that—have you thought about that?

Mr. CROSS. Yes, very much. In fact, I am convinced we have to have a third party. We have to have a third party to bring the thinkers together and let all the issues be laid on the table. So there is no question this cannot be a product of FSIS, that this cannot be a product of FDA or CDC; or perhaps even Government. We would need the third party to bless it and make sure it happens in an orderly fashion.

Mr. PETERSON. So, in other words, up there, to boil this all down, the Department is, or your agency will focus on getting to a risk-based system, to come up with a plan of how we do that. And you are not going to piecemeal it any more; you are going to try over the next couple of years to figure out what the new system will look like and get working on it?

Mr. CROSS. Yes, absolutely.

Mr. PETERSON. Well, we appreciate that. Thank you.

Mr. CROSS. Thank you, sir.

Mr. PETERSON. Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Ewing.

Mr. EWING. Thank you, Mr. Chairman, and before I ask any questions, I would like to note that Congressman Pat Roberts had several questions he would like to give to Dr. Cross for him to respond to; and our staff will take care of that, with your permission.

Mr. STENHOLM. Without objection, his and any other written questions, if there are any, will be submitted for the record.

Mr. EWING. Thank you.

[The material follows:]

RESPONSES TO QUESTIONS FOR H. RUSSELL CROSS, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, REGARDING USDA MEAT INSPECTION PROGRAM

House of Representatives
Subcommittee on Department Operations and Nutrition,
and Subcommittee on Livestock,
Committee on Agriculture
Washington, D.C.
Tuesday, March 16, 1993

MR. ROBERTS: Are there management practices in handling livestock on the farm that affect the pathogenic microorganism load and/or persistence in individual animals or herds?

DR. CROSS: USDA's Food Safety and Inspection Service (FSIS) does not have regulatory authority on the farm. However, USDA's Animal and Plant Health Inspection Service (APHIS) is directly involved in animal and plant health on the farm and has broad authority for the prevention, control, and eradication of infectious diseases of animals on farms and in marketing channels. This includes authority for the tracing of infected animals to their farms of origin, epidemiological investigations of disease outbreaks, and appropriate eradication or control procedures. APHIS is currently involved with pre-harvest risk reduction of Salmonella enteritidis in table eggs.

USDA's Extension Service (ES) also has a role in on-farm activities. ES identifies relevant research related to on-farm activities and validates research in existing production systems. The answer to this question and several of those following is based on USDA's current understanding of the research literature and extrapolation of the situations that lead to Salmonella contamination in livestock as an example of how other microbial contamination may develop on the farm.

We know that several management practices in handling livestock on the farm can affect the pathogen load. For instance, stress and nutritional status can affect the immune system in animals enough to alter their sensitivity to these organisms. Second, animal feed supplements and protein concentrates may contain microbial contamination. Third, natural carriers of pathogenic organisms, such as rodents, birds, insects, wildlife populations, and other infected farm animals, may carry these same organisms and reintroduce them into the animal population. Fourth, manure disposal methods may also be a factor. This is why a multi-factorial approach, incorporating biosecurity and Hazard Analysis and Critical Control Point (HACCP) techniques, may be the most effective at the farm level.

MR. ROBERTS: Are there on-farm testing procedures and epidemiological techniques that will appropriately monitor incidence/prevalence of these pathogens in food animals?

DR. CROSS: FSIS has developed an on-farm test for Salmonella. Also, APHIS has conducted prevalence epidemiologies and surveillance programs for detecting and identifying E. coli 0157:H7 in cattle. APHIS has conducted studies for several years on the pre-harvest risk reduction of Salmonella enteritidis in table eggs. Research continues on developing better on-farm testing methods to aid in determining the prevalence and incidence of disease, epidemiology of disease and better disease detection.

MR. ROBERTS: What is known about the mechanism of introduction of these organisms into the food chain on the farms or before the processing plants? For example, is it known how these organisms spread from animal to animal on the farms? Are intermediate hosts important? Are stress factors during production factors in the incidence and spread of these pathogens?

DR. CROSS: The factors discussed above -- stress, nutritional status, animal feed and manure disposal, etc. -- have a role in the introduction of pathogenic organisms into farm animal populations. In addition, mixing of animals from multiple sources during transport can encourage the spread of organisms. For instance, when small numbers of animals are marketed, these animals are often commingled to fill a vehicle. This could lead to contamination of animals that left the farm uncontaminated by animals from other facilities.

MR. ROBERTS: Are there on-farm management initiatives that can economically limit or eliminate infection by pathogenic organisms in food animals?

DR. CROSS: On-farm management and husbandry initiatives that address the factors mentioned above--stress, nutritional status, and manure disposal--can help to eliminate infection by pathogenic organisms in food animals.

MR. ROBERTS: What plans does the agency have for pre-harvest, in other words on-farm, investigations of food animal carriers of pathogens and of management practices to prevent introduction of these pathogens into the food chain?

DR. CROSS: FSIS recently released its Pathogen Reduction Program. A copy is enclosed. Pre-harvest production activities are an important part of that program, and FSIS is working with APHIS and other USDA agencies in pre-harvest efforts.

Unfortunately, scientists do not know with certainty which animals are most likely to be harboring human pathogenic organisms. Because scientists cannot tell us with precision

where and why the organisms appear, it has not been possible to design on-farm programs that will assist producers in making sure that their animals are not the source of dangerous bacteria. In addition, human pathogens are often normal flora for food animals such that animals will not necessarily appear ill. [redacted] harvest production activities are designed to obtain answers to the underlying scientific questions, and use those answers in conjunction with basic animal identification information to build a better pathogen prevention system for animals destined for food.

These activities are:

--On-farm epidemiological investigations of food borne enteric bacterial pathogens, using E. coli 0157:H7 as a model, to determine the characteristics and risk factors associated with infected animals.

--Animal ID and traceback programs so that meat-borne problems can be traced back to their on-farm origins. Such requirements are the basis for effective pathogen controls and are also the foundation of prevention programs that are beneficial to both producers and customers.

--Pathogen prevention programs to assist producers in eradicating and controlling disease organisms of public health concern. Models will be developed based on experiences of other countries such as Sweden and Denmark as well as outcomes of U.S. on-farm investigations combined with resources from producer groups and assistance providers such as APHIS and ES, the American Veterinary Medical Association, and universities.

Mr. EWING. I am sorry I was late; and I will admit several things, one being that I am no expert on food inspection procedures or where we stand today. So some of my questions may be redundant, but if you would go along with me on that.

Do we have a real emergency in America today in food inspection?

Mr. CROSS. No, we do not. As I have stated previously, I think we have the safest meat and poultry supply in the world, but we have to do everything humanly possible to prevent the kind of outbreaks we have recently had with *E. coli* in Washington State.

Mr. EWING. How do you compare America's system with those of other developed countries in the world; are we as good or better?

Mr. CROSS. I think we are better. Of course, I am slightly biased. But we spend a lot of time with other countries, particularly the ones that export to this country. There are some things we could learn from them. We have a group called the quadrilateral, which is Australia, New Zealand, Canada, and the United States; and we meet once a year with my counterparts in the other countries to discuss how we are doing things and how things could be improved.

But, basically, I think we have the best system in the world.

Mr. EWING. I believe that if we do have—and I think we do have—a very safe food supply and food inspection system, that is because we have worked at it and it has not just happened. And we have to continue to work at it and try to keep it the best.

I also believe in my years of experience that sometimes Government tries to legislate so that every human tragedy is avoided. I also believe that is totally impossible.

Would you comment on that in regard to the recent problem that we had? Do you think you can devise systems, regardless of cost, that could prevent that from ever happening?

Mr. CROSS. No. In fact, I think it is imperative we tell our consumer and our public that we very likely will not be able to guarantee them a zero pathogen product in the future. What we will do is tell them about that product and about how to handle that product and how to be involved in the food safety program.

We will do everything possible under the new system to reduce the pathogens, but total elimination is not in our framework for the near future.

Mr. EWING. Well, that would be how I would assess it, too, Dr. Cross. And I guess I would just say that I wish you the very best in your research in working out the system, but I would admonish you that the system has to be something we can afford.

We have a good system. It cannot be something we cannot afford, and we should not be put in the position of saying to the American people, we are not going to do this system because we cannot. We want to keep our system up to date, as accurate as possible, but we cannot avoid all human tragedy and we should not try. We should build that expectation among the American people.

Mr. CROSS. I couldn't agree more.

Mr. EWING. Thank you.

Mr. STENHOLM. Dr. Hughes, what is the extent of the resources that CDC puts into the identification of foodborne disease outbreaks?

Dr. HUGHES. In fiscal year 1992, we spent a total of $3,350,000 on foodborne disease issues at CDC. Of that total, approximately $350,000 was spent on *E. coli* 0157:H7. During the current fiscal year, the level is approximately $2.9 million.

Now, we will probably end up spending more than the $350,000 on *E. coli* as a result of some redirections we have done in response to the outbreak that has occurred, and we, of course, don't yet know what the resources will be for fiscal year 1994.

Mr. STENHOLM. What was your total budget for 1993 at CDC?

Dr. HUGHES. The total budget for CDC for 1993 was approximately $1.7 billion.

Mr. STENHOLM. $1.7 billion. And we spent $3,350,000 on foodborne diseases. What would be wrong with a conclusion that someone would reach that CDC believes foodborne diseases is a low priority in the total scheme of that which you look at as your responsibility?

Dr. HUGHES. Well, we have many diseases that we deal with and many other issues that are dealt with at CDC. For example, within our National Center for Infectious Diseases, we have 130 diseases and syndromes we deal with.

Across CDC, of course, the breadth of issues and diseases dealt with is quite wide. For us, in our Center, foodborne disease is a very high priority.

Mr. STENHOLM. It is a very high priority, I understand that, but the budget that we are putting into foodborne diseases is very low compared to the total budget. Can you help me understand, if you say it is a high priority, are you asking for more money in the 1994 budget; are you asking for more money specifically for foodborne diseases?

And in so doing, internally, given the fact we are going to be under tremendous budget restraints in all of our discretionary spending for the next 5 years, given we are asking for a freeze, in the scheme of prioritization, can you share with me and the subcommittees what your current thought processes are as you determine what the higher priorities are?

Are you going to recommend additional money to be reprogrammed?

Dr. HUGHES. As I said, we have already redirected some resources within our Center during the current fiscal year to help us deal with the *E. coli* 0157:H7 investigation; and we hope that we have effectively made the case for the continuing importance of foodborne diseases generally.

And as I mentioned earlier in some of my comments, we feel that foodborne diseases well illustrate some of the issues that are brought out in this Institute of Medicine Report, the fact that we are continuing to encounter new foodborne pathogens and we are continuing to encounter new problems associated with transmission of foodborne pathogens that have been recognized for some time.

Mr. STENHOLM. Mr. Harman, in your report of June of 1992, concerning the food safety, quality, uniform risk-based inspection system, you indicate—and in your work of investigating the FSIS—that you attribute a lot of things to FSIS. The Processed Products Inspection Improvement Act of 1986, which provided for less than continuous inspection and a more science-based food inspection sys-

tem. You state in your report that they indicated that it was providing some successful work, but they stopped it because of criticisms of the program.

In your investigation, did you confirm the alleged successes of this program toward the reduction of pathogens in our food supply? Did you confirm that or were you reporting what FSIS told you?

Mr. HARMAN. I stated there, as they told us; but let me have Mr. Zadjura quickly address that.

Mr. ZADJURA. Mr. Chairman, that was the discretionary inspection, as it was called. Basically, it was designed to reduce the requirement for daily visits to processing operations, that because of either the nature of the operation—for example, a simple cut-up operation, or because of the track record of that processing operation in following FSIS regulations, because of those factors the level of inspection would be reduced.

Now, when that was proposed, it was very controversial. Some viewed it as just a way to do away with more inspectors and turn more things over to the industry. FSIS did do some pilot programs, and essentially it was looking at compliance with existing rules and regulations. And in most cases, that does not really apply to pathogen reduction.

The program, in the sense the plant is still kept clean, still appeared to have a sanitary appearance and still appeared to produce a product that at least visually or organoleptically was OK, FSIS indicated to us they thought they worked well.

A similar program for streamlined inspection for cattle, some studies looked at it by—I forget the group right now—Dr. Cross can, I am sure, add it—indicated that in the case of the streamlined inspection system for cattle, which is slightly different, it was looking at slaughter, and it was allowing industry to do some of the cutting of tissues and presentation of tissues and stuff like that in lieu of an FSIS inspector.

The indications were in that case, because it required—and this was a study looked at by an outside group—the indications were that it was actually producing a better, cleaner, probably microbially safer product because the plants had——

Mr. STENHOLM. Do you have an opinion on whether that was factual or not?

Mr. ZADJURA. In the case of the streamlined inspection system, like I say, a body of outside experts looked at it; and they concluded—in looking at what they did and their reports, we basically concurred that the streamlined inspection system was producing meat that was at least as good as that being produced under traditional inspection.

Mr. STENHOLM. Well, that was the same information that was presented to me as chairman of the last Livestock, Dairy, and Poultry Subcommittee during that same period of time; and yet we still were subjected constantly to criticism, to the point at which FSIS finally, in their judgment, concurred to by the industry, that it was no longer smart to continue along this line.

Mr. HARMAN. I think that is the reason—and we are seeing it now in the current work we are doing for you, in talking to some of the consumer groups and talking to some of the inspectors—there is a definite lack of trust, a lot of questioning about the mo-

tives. And Congressman Peterson started to get at it, when he said, we don't really trust you to have it at your place; we want you to have it someplace else.

That is a real key part of this process, is getting those stakeholders to buy in. That is probably why it didn't work the first time.

Mr. STENHOLM. I agree to that. Let's stay on the issue of trust for just a moment.

Again, Dr. Hughes, I want to come back to you, because, in my opinion, CDC is going to have to play a very critical role in developing trust in the systems that we design, congressionally or administratively, if it is going to have credibility with the consumer. It will have to happen.

I want to switch gears just a moment. I believe you say you have been with CDC for 19 years and have been working in this area, and you have attributed some facts to the last 15 years—is there anything that you can point to regarding imported meat product into this country that would confirm or deny the periodic concerns that we have about the safety or lack of safety of imported product?

Dr. HUGHES. Let me make one comment and then ask Dr. Cohen if he can speak specifically to imported meat products. I would just like to say that I agree with the other people who have testified that we have the safest food supply in the world.

Mr. COHEN. The last that I remember about specific concerns about imported products was during the late 1970's when we were dealing with precooked roast beef, and there was some issues raised about specific *Salmonella* serotypes that contaminated the products and that they might have been present in beef that was imported, which was then handled, cooked, and processed in the United States.

The processes that were changed subsequently led to safe cooking of those products and would have reduced any risk to the consumers.

Mr. STENHOLM. Is there anything that you have discovered in your work regarding foodborne illnesses that you would want to tell us on this committee that we, in our inspection system, redesign on the track I and track II approach that Dr. Cross is talking about? Would you raise a yellow flag to us right now that would say that, yes, imported product is something that you should take a greater look at because of the potential safety, or lack thereof, of imported product versus the product that we produce in the United States that is inspected under the system that we now have?

Mr. COHEN. I think, based on our data, our greatest concern as a food risk would be microbial contamination of any food product. I think it would be helpful to have data which would compare both domestic and imported products that would be potentially able to target any regulatory action.

Mr. STENHOLM. And we don't have that data today? You have nothing in the work that you have done or are doing that gives us any benchmark today?

Mr. COHEN. In most instances, we do not have data that traces meat back to its ultimate source. We have data related to human disease and the factors that are involved in those outbreaks; most of those do not go back further than that.

Mr. STENHOLM. Dr. Hughes haS something to say and then Dr. Cross.

Dr. HUGHES. Let me just say in closing that I appreciate your interest in this, and I think, again, it highlights the need for us to continue to emphasize and improve foodborne disease surveillance in this country, because it is from the detection of disease and subsequent investigation that we will be able to develop data to allow us to better address your question.

Mr. STENHOLM. As we proceed down the track I and the track II in doing what needs to be done from the legislative, and then working cooperatively with the administration, it is extremely important that we maintain credibility; because constantly we have the allegations that meat entering into the United States is not subjected to the same criteria and is, therefore, less safe.

That builds a concern in the consumers' minds because, as we all know, meat tends to get mixed up, and we often have maybe four, five, or six different countries from which the meat arrives and is ground up. And, therefore—this is not a critical control point in an HACCP system, but it is a consumer control point in the political system.

And this is what I was trying to get at to identify any reason to raise a red flag today based on any information you have that would suggest this is a critical consumer point, and I believe you have answered.

Dr. Cross.

Mr. CROSS. One thing I forgot to mention, Mr. Chairman, is anything that we do on track I, and anything that we do on pathogen strategy, our friends across the water and elsewhere, North and South, are going to have to do exactly the same thing.

We already know, for example, that many of the countries that are major customers of ours have already started their own microbial baseline projects and are getting ready to put HACCP systems in and monitor critical control points. Many of these countries have the same problems we have dealing with pathogens; they don't have any magic solutions. Most of them are looking to us for solutions.

I want to give you assurance that whatever we do domestically, it will be done internationally as far as products coming into this country.

Mr. STENHOLM. Any comments along this last line of questioning from either of you?

Mr. ZADJURA. Yes, Mr. Chairman, we have done three or four studies so far on the imported meat coming in from Canada and the changes that were made under the NAFTA agreement. We have consistently, I think, supported FSIS' position and all our work in Canada with the Canadian Government, with the Canadian groups and FSIS is that that meat and poultry, a limited amount of poultry comes in from Canada. But that meat certainly meets our standards and is as good, essentially, as the meat in this country.

That is true also for the other countries that are exporting to the United States; as Dr. Cross could tell you, they essentially approve every single plant, that it meets our standards, and that the inspection system of those countries meet our standards.

There are unfortunately—they suffer, as Dr. Cross said, from the same problems we have. They don't necessarily do any microbial testing, and it might be hard, therefore, to link it up with disease; but there is virtually no difference that we can see, or all the statistics that we have looked at—that includes CDC statistics, State statistics, statistics from foreign governments, FSIS—that indicates that there is any problem other than the exact same kind of problems we occasionally have here with our own product.

Mr. STENHOLM. Just a quick observation with that, and I thank you for those comments, because I believe them to be as accurate as you believe them to be, based on everything that we have looked at and seen.

An observation here, going back to credibility and hopefully to give everyone an indication of where this committee is going to be coming from, because credibility is it: Consumers have to believe what we are telling them, and right now the consumer does not believe GAO, doesn't believe USDA, doesn't believe CDC, and has even less confidence in the Congress of the United States.

And they can always prove you wrong. There will always be that unfortunate incident that occurs, that creates a tragedy like we have had just recently. It was always going to happen, because we don't live in a perfect world, and no matter how many laws we pass or how perfectly we design the system, we cannot design a perfect system. But the challenge we have now is to try to design a better system, and in the end, it has to be one that will have credibility, that will have believability, and that is what we are lacking today.

We are lacking it for many reasons, but, to me, that is perhaps the one critical issue that we need to resolve legislatively and administratively, and in the eyes of the American people and the ears and the beliefs of the American people.

Mr. Volkmer.

Mr. VOLKMER. Thank you very much, and if somebody has already replied to these questions just let me know.

Dr. Cross, Mr. Harman, what role do you envision for microbial testing in the future?

Total future, not tomorrow or next week or anything, but totally in the future.

Mr. CROSS. Basically, heavy monitoring, heavy baseline data collection, so we know how the industry is improving or not improving or how our systems are working; and also significant monitoring in the early stages of the critical control points that we identify, from the farm all the way through the system.

Eventually, we expect to see the industry also doing a great deal of their own microbial monitoring. I don't think the industry can afford to have a regulatory agency come into their facility and collect pathogen data without knowing where we are heading and what we are going to do.

So, basically, we envision a heavy microbial footing for the industry and for the Government regulatory agencies for the remainder of this decade.

Mr. VOLKMER. When you talk about monitoring, you mean taking a sample of the supply, whether it is poultry or beef or pork or anything else, and have those samples tested just for microbes to see

what is or is not there, and use that as a basis for a future determination?

Mr. CROSS. Yes, sir, we are doing it for two reasons. One is the baseline, to see where we are with regard to pathogens across an industry or a commodity. But, second, we do it at a critical control point, not just to see how many microbes there are but to see if the process is under control. And we will be able to tell at some point whether the process is out of control and be able to work with that company to get it back into control.

Mr. VOLKMER. Now, here they are not talking about testing every chicken, every carcass or anything like that; right?

Mr. CROSS. Absolutely, no.

Mr. VOLKMER. But in addition to checking the animal itself, or parts of the animal, you are also going to be able to do testing on packers, facilities and things like that, and right up and down the line?

Mr. CROSS. Yes, sir; very much so.

Mr. VOLKMER. Could you give me some idea, not necessarily right now, but in writing, about the number of, type of microbial or bacteriological pathogens that we may have to test for?

Mr. CROSS. Yes, sir.

Mr. VOLKMER. I would very much like to have that in writing for the record. And can you give me an idea of what this monitoring-type thing, how much that is going to cost, your cost? And don't estimate. We don't know what the packers and the companies are going to do, but what would you think?

In other words, what are we going to have to do as far as your funds are concerned, and reallocation or additional or what?

[The information follows:]

RESPONSES TO QUESTIONS FOR H. RUSSELL CROSS, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, REGARDING USDA MEAT INSPECTION PROGRAM

House of Representatives
Subcommittee on Department Operations and Nutrition,
and Subcommittee on Livestock,
Committee on Agriculture
Washington, D.C.
Tuesday, March 16, 1993

Dr. CROSS. Allow me to take each of your questions in order. With regard to testing for pathogens up and down the line, the answer is yes, we anticipate that microbial testing would occur at various critical control points throughout the animal production and food processing continuum. For instance, we expect that on-farm testing would be desirable in some cases so that animals known to be carrying certain pathogens would not be presented for slaughter. In certain cases, microbial testing of the slaughterhouse and processing plant environments might be important controls. In other instances, microbial monitoring of ready-to-cook products such as ground beef may be essential to determining if such product should leave the Federal establishment with the mark of inspection.

As for the number of microbiological agents we will have to test for, let me say that although the list of foodborne diseases and agents that cause them is long, only about 20 are known to be transmitted by foods with a consequence and/or frequency serious enough to cause concern. During the period 1973-1987, outbreaks attributed to consumption of meat and poultry products were caused by only 10 of these organisms.

In some instances it may make more sense to check for indicator organisms which are not pathogenic in and of themselves but are likely signs that pathogens are present. Testing for indicator organisms is preferred where such testing is more quickly accomplished and where the regulatory penalties are less stringent.

With regard to the costs of microbiological testing, it is extremely difficult for us to provide the exact amount that will be needed at this time. We expect that as inspectors become better equipped with microbial analytic techniques, companies that have not already done so, will do much of this kind of testing themselves. This may permit us to use relatively low levels of random testing as long as compliance is demonstrated.

I can say that the President's FY 1994 budget request to Congress included $8 million to begin addressing pathogen reduction reduction in Track I. Of this $8 million, we anticipate spending approximately $2.5 million to conduct limited microbial testing of critical control points in selected beef slaughter and ground beef processing plants. This will include about 100,000 samples over the course of the year.

Mr. CROSS. Yes, it is difficult to pin down a number since we have not seen our final budget yet, but basically as we look at baseline monitoring for steers, heifers, cows, swine, or poultry, we are looking at between $2 and $3 million for that portion of it alone. For the HACCP monitoring and the critical control point in the early stages, we will also be looking at $2 to $3 million.

Mr. VOLKMER. Mr. Harman, would you like to mention anything in regard to this discussion?

Mr. HARMAN. I would reinforce what you said and what Dr. Cross said, that I don't think there is any way we should be doing microbial testing on every single piece of meat that comes through the process. The key thing here is to identify those, as I said earlier, those areas, those pieces of the process that represent high risk, and that is where you test.

The plant that Mr. Zadjura talked about was, I believe, a slicing machine that was showing up because something was testing, was showing up higher microbial load, and they were able to identify that and take action. It wasn't, they did it on each piece of meat.

So I agree, I don't think we should in any way be testing each individual piece of meat.

Mr. VOLKMER [assuming chair]. Thank you very much, Mr. Harman.

Unless there is someone on the panel who wishes to say anything else, we are going to excuse this panel. I appreciate your testimony.

Just a minute. The gentleman from Texas may have something else.

Does the gentleman from Illinois have any additional questions?

Mr. EWING. I have already completed mine, thank you.

Mr. VOLKMER. You have no more, thank you.

Let's make sure the gentleman from Texas does not have any more questions.

If the gentleman from Texas has any additional questions, he will send them to you in writing, because I am going to excuse you at this time.

You have been patient and helpful, and thank you very much. I appreciate your testimony and look forward to working with you to improve our inspection system. So thank you very much.

Our next panel will be Michael P. Doyle, director, center for food safety and quality enhancement, University of Georgia and member of the Food and Nutrition Board, National Academy of Sciences; Joseph Rodericks, senior vice president, ENVIRON Corporation, 1987 chairman, Committee on Public Health Risk Assessment of poultry inspection programs, National Academy of Sciences; Dr. R.G. Cassens, chairman, department of meat and animal science, University of Wisconsin; and Dr. James Denton, chairman, department of poultry science, University of Arkansas.

Gentlemen, if you will be seated, we will begin with Mr. Doyle. You each will be called upon to testify in the order your names were called. Gentlemen, your statements will be made part of the record and you may either review your statements in full or summarize however you may desire.

We will begin with Dr. Doyle.

STATEMENT OF MICHAEL P. DOYLE, MEMBER, FOOD AND NUTRITION BOARD, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, AND PROFESSOR, FOOD MICROBIOLOGY, CENTER FOR FOOD SAFETY AND QUALITY ENHANCEMENT, UNIVERSITY OF GEORGIA

Mr. DOYLE. Thank you, Mr. Chairman, I appreciate this opportunity to testify on behalf of the Food and Nutrition Board, which is a division of the Institute of Medicine in the National Academy of Sciences.

The U.S. Department of Agriculture has called on the Food and Nutrition Board 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, to recommend changes to the regulatory systems currently in place, and to recommend research to improve the safety of these foods. All three reports reached similar conclusions about the health risks posed by meat and poultry and the nature of changes needed to improve the inspection systems.

I have submitted written testimony as part of the record and shall simply summarize this testimony.

USDA's traditional meat and poultry systems have remained largely unchanged since the 1900's. They consist primarily of USDA inspectors examining specified organs of carcasses for visible lesions that may indicate that the animal was diseased before butchering. Traditional inspection also involves checking for proper dressing of the carcass, including removal of bruises and 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 the Food Safety and Inspection Service does test samples of meat and poultry products for microbial pathogens and chemical contamination, its monitoring is not designed to prevent public exposure or to eliminate risks to public health.

A full-fledged inspection system designed to meet public health objectives will require that the FSIS, first, support research to develop scientifically sound real-time sample methods for detecting contaminated meat and poultry; second, implement a comprehensive system for identifying critical control points in the production process for reducing hazards; and, third, develop a practical system for tracing animals back to the source to locate and remove possible sources of chemical residues or microbial 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 streamlined inspection system for cattle which is 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.

Finally, USDA, other Federal agencies, and the 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, food preparation, and serving methods in limiting food-borne disease.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Doyle appears at the conclusion of the hearing.]

Mr. VOLKMER. Dr. Rodericks.

STATEMENT OF JOSEPH V. RODERICKS, SENIOR VICE PRESIDENT, ENVIRON CORP., FORMER CHAIRMAN, COMMITTEE ON PUBLIC HEALTH RISK ASSESSMENT OF POULTRY INSPECTION PROGRAMS, NATIONAL ACADEMY OF SCIENCES

Mr. RODERICKS. Thank you, Mr. Chairman. I am here to offer testimony this morning on the review of meat and poultry inspection systems. My background includes 15 years as a scientist at FDA, specializing in the evaluation of health risks associated with foods, and more than 12 years as a consultant to industry and Government on assessing human health risks associated with agents in our environment.

In 1985, I was asked by the National Research Council to serve as chairman of the Committee on Public Health Risk Assessment of Poultry Inspection Programs. The committee was assembled at the request of the FSIS, and was asked to develop a risk assessment model to assist the agency in developing poultry inspection procedures that would best protect the public's health.

Our committee, which consisted of experts not only in risk assessment, but also in all the various technical disciplines related to the problems of both biological and chemical contamination, studied the problem for a year and a half and produced its report in 1987. I believe that what our committee had to say in 1987 is still relevant today and I will summarize a few of our key findings and recommendations.

Let me say, first, a little bit about risk assessment and of its importance in solving public health problems of this type. We should think of risk assessment as the most highly systematic means we have available for organizing our knowledge and our information about public health—whether biological or chemical origin—problems that arise in our environments.

Such an assessment is the only sure way for us to understand the magnitude of particular problems, and most importantly, provides the most systematic means available for identifying the principal sources of risk and, thereby, the types of actions and interventions that will most effectively reduce them. It highlights uncertainties in our knowledge, and because this risk assessment is a highly valuable guide to the types of investigations that are nec-

essary to develop risk management programs that are scientifically based, risk assessment is a key component of regulatory decision everywhere and is also an excellent guide to research prioritization.

In developing a risk model for FSIS, a kind of prototype if you like, we identify five stages in the poultry system where microbial or chemical contamination may occur: During production, slaughter, processing, distribution, preparation and consumption. Each of these stages requires its own type of risk assessment to determine the probability that contamination may occur, and our report contains detailed discussions of how each of these might be approached, the kinds of data that are necessary to answer risk questions and the kind of analysis needed.

We emphasized that such an assessment, guided by our model, would be a reliable and scientifically sound guide to identifying critical risk management points and for devising the most important remedial measures. We also emphasized additional investigations need to be undertaken before implementation of more effective public health programs can be envisioned.

Our risk model, we thought, properly applied, would provide a guide to the necessary investigations. Our committee, like many others, found the contamination of *Salmonella* or certain other microorganisms is the most significant public health problem posed by consumption of chickens. Current inspection procedures, however, rely heavily on visual and manual examination of each bird as it is readied for sale.

We found no evidence, and we searched quite hard, that such procedures provide effective protection against this type of microbial contamination. They certainly serve many other valuable purposes but this is not one of them.

Our committee recommended that FSIS develop the necessary data to allow shifting of emphasis from the current bird-by-bird inspection procedures to a system that involves more rigorous testing of a random sampling of chickens for consistent microbial contaminants. Some testing of this type is performed now, but we found it is not frequent enough, nor the results processed quickly enough, to ensure early detection of problems.

Most important, the programs that exist now are not adequate for establishing a sound data base for understanding underlying causes. Microbial contamination can occur at any or all stages of the poultry system and all stages need to be examined. Pathogens are commonly found in fecal matter and come in contact with the eatable flesh of the chicken during the scalding, plucking, and evisceration process.

During the production process, chickens may be fed impure grains or waters containing microbial or chemical contaminants and, of course, contamination may occur in homes during food preparation and in establishments as well.

As I have said, in developing the risk model for FSIS, we provided detailed analysis of each of these five stages. We do not know which stage or stages contributes the most to contamination problems, but the risk assessment model we have provided, we think, can be applied to identify the critical stages for devising appropriate remedial measures.

We recognize FSIS does not have jurisdiction to regulate poultry products beyond the slaughterhouse. It is, however, the Federal agency charged most directly with ensuring poultry is safe to eat. This is why we urged FSIS to take the lead in coordinating efforts with EPA, the Food and Drug Administration, CDC, State and local health departments to detect and prevent contamination at each of these five stages.

What do we think our report meant for consumers? Poultry is a nutritious and desirable part of the American diet. We did not want to discourage anyone from eating chicken. We did want consumers to be aware of the problem and to handle and cook chicken properly. The rules for doing so are so important that we suggested that labels describing proper cooking and handling be provided on poultry products at the time of sale.

We also proposed that FSIS develop education programs for workers in the poultry industry and commercial food establishments.

Our major findings, then, are these: Contamination of poultry products with pathogenic microorganisms such as *Salmonella* is now occurring at high levels. While the data are not complete, and while poultry is not the only source of these microorganisms, we believe this contamination, wherever it occurs, plays a major role in the millions of cases of food poisoning occurring each year.

The FSIS and other relevant authorities and the poultry industry should work to minimize the contamination by: Random sampling of chickens during processing, for both microorganisms and chemical contaminants, using contemporary statistically based quality control procedures; monitoring of feed, water, and other environmental influences during production; and, most important of all, conducting studies at all stages to determine the major sources of contamination and to learn how to control them.

We also suggested labels be provided on poultry products to inform consumers about proper cooking and handling. The risk assessment model we developed provides a systematic framework for undertaking these activities and we recommended that FSIS apply it to guide its risk management programs.

What I heard this morning from Dr. Cross sounded very much like the kinds of things we recommended that FSIS undertake. It seemed to go very far in the direction that we suggested back in 1987.

Thank you.

[The prepared statement of Mr. Rodericks appears at the conclusion of the hearing.]

Mr. VOLKMER. Thank you, Dr. Rodericks.

Dr. Cassens.

STATEMENT OF ROBERT G. CASSENS, PROFESSOR, DEPARTMENT OF MEAT AND ANIMAL SCIENCE, UNIVERSITY OF WISCONSIN

Mr. CASSENS. Mr. Chairman, members of the subcommittees, thank you for inviting me in this morning to comment on the present meat and poultry inspection system. I am Bob Cassens, professor of meat and animal science at the University of Wiscon-

sin. I have submitted a written statement and request it be entered into the record.

I believe the present meat and poultry inspection system works for the intent it was designed more than 80 years ago, and that is to eliminate diseased and damaged pieces of meat from the human consumption chain, and also to ensure that the operations are done in a sanitary and appropriate manner.

I believe, however, it is time to modernize and improve the system. I see three ways to do that: By adopting existing scientific technologies which have been proven to be effective and safe but which are not now used; to utilize scientifically trained people; and to develop scientific technologies for the future.

The simple conclusion, I think, is that more science should be adopted into and used by the meat inspection system. Allow me to expand very briefly on my three major points.

First, I will give some examples regarding scientific technologies that, if adopted, would be effective, and also safe. Irradiation: More than 30 years of research and debate have shown that irradiation can work. More recently, rinses or sprays of carcasses have been shown to control surface contamination. And finally, and mentioned several times already today, HACCP, hazard analysis critical control points. To me, that is a system which is preventive rather than reactionary to something that has happened. I think it could work over the total system, again, as you have heard many times, from the farm to the table.

Why are these items not being used? There are some regulatory barriers. Professional food safety activists have influenced consumers and the media through the years and trained them very well to be antitechnology, and at this point in history, I think the industry just is not willing to take a risk of introducing technology when they are concerned that consumers won't accept it.

The second major point: We must have trained people. If we are to introduce new technologies and sciences, we must have people trained in those sciences. We must have people who can make judgments and evaluations. Also, I think there should be a genuine and a sincere attempt to educate the consumer.

Third: Future technologies. I will mention two examples, again all of which have been talked about already today, but there is a powerful need for rapid, accurate methods; and, second, there is a need for trace-back procedures so that sources of organisms, pools of organisms can be identified; and, also, there is a need for baseline histories so that trends can be viewed and something can be done about trends that are seen.

My conclusion is, then, regarding meat and poultry inspection, some complex food safety issues have been identified. To solve these problems, I think we need science and technology. Remember, however, that there is no absolute in science, and I am also quite certain there is no 100 percent in the food safety issue. However, by using science and technology, I think we can get as near perfect as possible.

Thank you.

[The prepared statement of Mr. Cassens appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you very much.

Dr. Denton.

STATEMENT OF JAMES H. DENTON, PROFESSOR, DEPARTMENT HEAD AND DIRECTOR, CENTER OF EXCELLENCE FOR POULTRY SCIENCE, UNIVERSITY OF ARKANSAS

Mr. DENTON. Mr. Chairman, thank you for the opportunity to speak with you today and share some thoughts with regard to food safety in the meat and poultry inspection service.

I am currently serving as the head of the department and director for the center of excellence for poultry science at the University of Arkansas. Prior to that time, I spent 15 years as an Extension educator with the Texas A&M University system and 5 years as a researcher with that same system.

What I would like to do is request that my statement be entered into the record, and I will try to summarize the comments here, because many of the points have been stressed in the discussions earlier. But I feel it is important that we put these in a proper context.

The current meat and poultry inspection system has the perception as being a very flawed system and outdated, that it is not scientifically based. This is an unfortunate situation because I believe that it ignores many of the very positive advances that have been made through the collaboration of the meat and poultry industries and the inspection system in working toward the solution of food safety concerns over the history of the organization.

We have been addressed earlier about the role of inspection for the elimination of obviously diseased animals, physically damaged, or those that would be contaminated with foreign material. This was the initial goal of the meat and poultry inspection system.

As our scientific knowledge has increased, more scientific means have been applied to the system. This has resulted in improved techniques, not only for processing, but for the inspection system.

The questions that we have to address today are really, I think, two. They are fairly simple questions. The first one is: Are we doing the very best job that we can of assuring the safety of the meat and poultry supply? If we are perfectly honest with ourselves, I think that the answer that we give first is that, yes, we are giving our best effort; but no, it is not where we would like to see it in the future.

The second question, probably more significant question, is: Should we abandon the current meat and poultry inspection system? Being honest with the answer for that question, I think we have to say no, because the system has served us very well in the past. I do think that the answer in the future is yes, as we shift to a greater application of science-based inspection systems. We must not allow this system to become inflexible in the application of the scientific principles that we need to move forward.

The support for the adoption of the HACCP model as a basis for inspection appears to be a very radical shift in the process. In reality, I think what we are really faced with is a redirection of our existing resources into a more efficient system. The science basis for this, in addition, will require effective training for the personnel involved in the application of the HACCP system, whether they be in the industry or whether they be in the inspection service.

This is not the first time that you have heard education and training mentioned this morning. And I will assure you before I finish with my statement, it will not be the last time.

If the HACCP model is applied, it will place a great deal more responsibility on the industry. HACCP is an industry management tool. Meat and poultry inspection should obviously have oversight and monitoring for this particular program.

The meat and poultry inspection system is a process. The inspection system that is in place in 1993 is not the same as in 1983 or in 1973. It is not a static system. It must be allowed to change with the changes in our science information.

There is also a great deal of debate about the value of science-based discussions and science basis in the decisionmaking process as being separate from value-based decisions. In my opinion, the scientific basis and the value basis are intertwined. The science provides the accurate information that is necessary for good value-based decisions. If not the science, then we are to rely on fear, superstition, and misinformation. And I do not think that these are acceptable ways to make the decisions.

Meat and poultry inspection is at a crossroads. There will probably be some changes that have been forced by the more recent events with the outbreak of *E. coli* 0157:H7. Inspection, as a function, is part of the processing and marketing process, as is science a part of a process for the expansion of our knowledge.

As we look to the origin of our scientific information that we need to make these decisions, there are really three fairly simple sources for the most effective information that we have. One is the industry-associated research; two is the research that comes from universities and from Government laboratories; and the third area is that of the regulatory community themselves, meat and poultry inspection included.

I was interested to hear the comments earlier by the gentleman from the Centers for Disease Control with regard to what they have accomplished. Coming from an extension education background, I think that a lot of the information that they have previously published in our scientific journals forms the basis for a lot of our more effective education programs. But taken collectively, they provide an excellent picture of where we need to go in the future.

A lot of the information that we know about time and temperature relationships, the sources of contamination that we have learned about to this point, many of the control and reduction systems that are applied in production and processing, as well as the impact of mishandling in the food preparation sector are the result of data from these agencies and the information that they provide.

In driving this process, I feel that it is important that we have information from scientific journals not necessarily from the news media.

In many cases, this information is event-driven rather than process-driven and, as a result, has a tendency to be much more sensational and emotional. What we need to try to do is make the best use of our very limited resources in answering very complex problems.

The specific recommendations that I would like to offer for the improvement of the system—I feel that we have a tremendous opportunity to make the transition from a visual-based inspection system into one that is much more science-based. We probably do not need to be looking back to traditional methods of inspection. We must look forward to the science-based, more efficient use of our resources.

I really think that the track II that Mr. Cross has outlined in his statement is probably the most effective way to go with this. This is based on a very sound principle that hasn't been stated this morning, but I think it is very important. We must build safety into meat and poultry products because they cannot be inspected into these meat and poultry products.

The most effective management tool that we currently have available is the HACCP model. The hazard analysis critical control point program, as a subset of total quality management, is not an inspection system; it is a management system that puts the responsibility on the industries.

Another point that I think we need to talk about in the application of the HACCP model is the difference between control points and critical control points. We have heard critical control points mentioned all morning. As we look at control points, these apply primarily to products that are of a raw nature.

As we move into processing that requires cooking, the application of critical control point principles comes into play. The greatest danger that we have in applying—or I prefer the term "misapplying," HACCP as an inspection system for raw products is that we unrealistically raise the consumers' expectation that raw products can be free of pathogens. This is not technologically possible with any of the available technology that we have today. Animals do not live in sterile environments. We do not have the capability to selectively eliminate pathogens from our meat and poultry animals simply because we do not control all of the known points where they can enter into the system. Humans do not live in a sterile environment, and points of recontamination exist all along this food marketing chain. The most significant of those are after it leaves the processing plant.

Now, before someone misinterprets this, this in no way diminishes the responsibility of the industry. It has been their obligation to provide a safe and high quality meat and poultry product all along; and it is still their objective today.

What is necessary is that we provide this product with the highest safety margin possible. The greatest contributions of the meat and poultry inspection should be the high priority adoption of sound science-based inspection systems, continue to serve as a resource for information which supports educational programs for all levels within the marketing system—recommendations that originated in the 1992 National Food Safety Workshop held here in Washington, DC, sponsored by the Cooperative Extension Service from Arkansas, Texas, California, Indiana, Maryland, and Virginia—is that education is the most effective solution to our food safety issues. This begins with the producer. It extends into processing, to food service, food retailing, and ultimately to the consumer.

The National Educational Forum for Food Safety Issues that was developed as a specific recommendation of the National Food Safety Workshop has, as its mission, to encourage the utilization of science-based information relative to food safety. The initial project of this forum is to jointly sponsor with the American Medical Association a conference that is targeted to medical professionals in November 1993.

The fact that these professionals came together and worked in planning this particular conference is a clear signal that education is a very important part of the solution to these problems. The value of the Cooperative Extension Service, as the most credible source and the most effective delivery system, cannot be overlooked. They are the most effective way to reach a wide variety of audiences with the research information that is generated by the research in the land-grant university system.

In summary, what I would like to recommend to the committee is to support the adoption of HACCP as the most effective management tool for application by the meat and poultry industries; support the shift of the meat and poultry inspection system to a sound science-based system such as HACCP, with meat and poultry inspection to have the oversight and monitoring responsibilities of that system; support the process of education as the most effective solution to dealing with food safety issues; and recognize the Cooperative Extension Service as the most credible source and most effective delivery system with regard to that information.

Mr. Chairman, I thank you for the opportunity. And I will be happy to entertain questions at the discretion of the committee.

[The prepared statement of Mr. Denton appears at the conclusion of the hearing.]

Mr. VOLKMER. We are going to have a few questions.

I don't know if anybody wants to answer it or not—as I sit here and listen to this and thinking of the future, and let's say 10 years down the line that we are able to come up with a test whereby I can test every chicken that is coming down that line, even though I only have two seconds to look at it, but science being what it is, let's say we have been able to do that, every meat, carcass, and everything else we are able to test.

What do we do after we test and we find in each individual piece of meat—what do we do with it 10 years from now?

Anybody want to answer that? Anybody?

Mr. DOYLE. I might take a crack at it, if I understand the question correctly.

Mr. VOLKMER. Science has advanced to the point where I can determine every piece of meat, whether or not it has a pathogen, whether it has a microbial pathogen, whether it is in a beef carcass, pork carcass, whether it is on a chicken, turkey, anything else, I can detect it. Now, what do I do with it?

Mr. DOYLE. Assuming that the incidence is low, you may be able to handle that meat differently than the rest of the meat.

For example, you may put it into a fully cooked product, versus a product that would be sold fresh—uncooked—at retail.

Mr. VOLKMER. All right.

Mr. DOYLE. One example is the *E. coli* problem that we presently recognize. Some studies have suggested an incidence of 1 to 3 percent of this organism in ground beef.

If we are able to screen cattle before they get into the slaughter plant and identify those that are carriers, perhaps we could use them for different purposes.

Mr. VOLKMER. Maybe science can come up with a way, like a spray where we can decontaminate it, possibly?

Mr. DOYLE. Well, we have determined that organic acid sprays can reduce or eliminate in some cases, certain types of these harmful bacteria.

And we have also learned that, at the other extreme, using a basic application like trisodium phosphate may kill other types of harmful bacteria. And these treatments may be used in combination. It is my understanding they are being considered by Mr. Cross and the group at FSIS for potential application.

Mr. VOLKMER. I think for the purposes of the record it is true, too, Doctor, that different pathogens affect people differently. There are some that are a lot less harmful than others, correct?

Mr. DOYLE. That is correct.

Mr. VOLKMER. And I don't think, as we have addressed in this hearing, we have addressed that at all. And I think we ought to realize that and have that in the record that not all are going to kill me, correct? It might make me a little sick, but it is not going to kill me.

Mr. DOYLE. That is correct.

Mr. VOLKMER. And I think there is general agreement here among the panel that what we are doing can be improved and, I think—after listening to USDA and FSIS that they are planning to do that.

But do you agree, also, that there is no way—and I think maybe one or two of your statements point out—that we are ever going to assure the public that meat supplies are 100 percent safe, correct?

Mr. RODERICKS. Yes.

Mr. DENTON. I don't think that we can do that.

Mr. VOLKMER. Not with today's scientific knowledge.

Mr. DENTON. Particularly if we are trying to indicate, to the ultimate user, that that product that comes to them is pathogen-free. The minute you say that, what they automatically hear is that that product is sterile or bacteria-free, not just pathogen free, but bacteria free.

Mr. VOLKMER. There is no way you can do that?

Mr. DENTON. No, sir.

Mr. VOLKMER. Now, let's get back to *E. coli* and what happened out in the State of Washington, as I understand, where it came from. That same beef that that hamburger came from probably had some steaks and roasts; did it not?

Mr. DENTON. Yes.

Mr. VOLKMER. I am sure that whole beef wasn't made into hamburger. Can anybody answer that? Or would you speculate? Anybody?

Mr. DENTON. I suspect you are correct. I don't know that.

Mr. VOLKMER. That cow or that steer came from somewhere. Even if it was an old cow from a dairy or someplace, everything didn't go into hamburger. I wouldn't think so, anyway.

What I am trying to get to is this: Where does *E. coli* usually come from in a cow? Where is it prevailing in the cow?

Mr. DOYLE. It is typically carried in the intestinal tract of a cow.

Mr. VOLKMER. That is correct. That is what I have always understood. It is intestinal. And, therefore, if you use intestinal parts, it is mostly used in hamburger, the parts there are—I don't know—I mean that is going to contaminate part of those parts, right, when it is slaughtered?

Mr. DOYLE. Well, there are different ways in which the feces can come in contact with the meat. Perhaps it is on the hide. The way cattle live, they defecate and sometimes lay in their feces. And, ultimately, when the hide is removed, it can contaminate the environment of the slaughter house as well as the meat on the carcass.

Also, if the intestinal tract is exposed during slaughter, feces could contact the carcass.

Mr. VOLKMER. Right. But it is more apt to be within the—at least I thought that as the steer was being slaughtered and those parts removed, there is the opportunity for some of it to be contaminated, correct?

Mr. DOYLE. Well, with *Salmonella* we have learned that the hide is a very important vehicle by which *Salmonella* can contaminate meat.

Mr. VOLKMER. From the hide?

Mr. DOYLE. From the hide.

Mr. VOLKMER. If we know that, then we know that we can do certain things, perhaps, to reduce the opportunity for it being spread, is that correct?

Mr. DOYLE. That is correct.

Mr. VOLKMER. I have no further questions.

The gentleman from Texas.

Mr. STENHOLM. Dr. Denton, you mentioned the initial cooperation with the AMA on a conference targeted to practicing physicians entitled "Food Safety and Food-borne Illnesses: An Opportunity for the Practice of Preventive Medicine" in November 1993. Has this been done before?

Do you have knowledge of previous instances in which the AMA has either been asked to or has involved itself in this question of food safety?

Mr. DENTON. Not to my knowledge.

Mr. STENHOLM. Dr. Rodericks?

Mr. RODERICKS. No, I don't recall anything significant.

Mr. DOYLE. The AMA has published a book in the past regarding food safety.

Mr. STENHOLM. Each of you has been very active in this entire subject that we are talking about. You have made recommendations; you have been very active and supportive of this committee in the past.

The reason I asked that question, as I posed the question to the CDC earlier in this question of credibility of whatever we do along the lines of the Food Safety and Inspection Service, and the attempt to assure the public that our food system is safe, that we

constantly are attacked by others who have a little different viewpoint and so often just enough truth to what they say that there is some credibility to it, and then it becomes a media spectacle; and then we have a problem within the industry.

And that is one that is a problem within the industry, but it does not serve the consumer in the long term either.

But it seems to me, as I mentioned, that CDC definitely has to be a part of the Food Safety and Inspection System. It needs to be there for obvious—to me obvious—reasons.

I also believe that the public health sector, in this case the AMA, for example, needs to be more involved in some of the day-to-day questions that you gentlemen deal with in the manner in which you advise the industry, in this case the meat and poultry industry.

Are we on the right track of suggesting that we ought to involve the public health sector more dramatically in this entire question? Or are there some pitfalls there that I might be overlooking?

Dr. Denton.

Mr. DENTON. I would like to try to respond to that. I am convinced that we have to be involved with the public health sector in this particular issue.

In looking back at a comment that I made in my opening remarks, one of the things that we have been able to learn from looking at the information that CDC publishes is what some of the primary causes of food-borne illness outbreaks are, not necessarily the source or the vehicle by which the outbreak occurred but what the true causes were.

And if we are very honest with the way we look at that information, regardless of whether we talk about the general consumer, the food service sector, or any other type of food preparation system, we find that most of the errors are attributable to human error in that process.

In looking at this, one of the things that we want to try to avoid, if we look at the entire marketing chain as well as the public health sector in trying to put the total picture together for the best information that we can provide, we have to do two things: We have to get the best people that are involved in the areas that impact food safety. We have to provide the most current technically, accurate information that we can find to avoid conflicting messages.

The one thing that will do the greatest amount of damage to any educational effort—and education I think is a very key part of this—is if the information from another source conflicts with the information from the first source.

The only way to resolve that is to get the involvement of all the parties that have a stake in the food safety issue on the same team looking at this in a much more comprehensive manner than what we have done in the past.

Mr. STENHOLM. Dr. Doyle and then Dr. Cassens.

Mr. DOYLE. I would suggest it would be helpful to have the medical community involved. But I think we need to go one step further and that is to go all the way back to the grade school level, where young children are educated in how to properly handle food.

And I think that is something we are missing today, that 20 or 30 years ago was in our academic programs.

Mr. VOLKMER. Would the gentleman yield?

Mr. STENHOLM. Surely.

Mr. VOLKMER. Something my wife has always insisted. Anybody in our house, before they handled any food, they must wash their hands.

Is that what you are talking about?

Mr. DOYLE. It is an important point, and properly cooking food.

Mr. VOLKMER. That is just one thing. Of course cooking and everything else, cleanliness is part of it; correct?

Mr. DOYLE. Exactly.

Mr. STENHOLM. And before you respond, Dr. Cassens, the manner in which I am asking you this question is, again, you—at least the three of you, represent universities.

The basic point is each of you believe that you are doing a darned good job in your university on the subject of what you are testifying here today. There is always a tendency of each of us to resist criticism, whether it be constructive or otherwise. There is a tendency on the part of all of us that we know the answer and that someone else really and truly is not necessary.

Quite often that involves funding which can lead to public criticism of our systems; and that is why, it seems to me, that we ought to at least explore the possibility of creating some kind of a peer review system that would include, for example, groups like the AMA; and other entities that would have credibility in the eyes of most of the American people. This peer group would review, for example, the work that Dr. Rodericks did in 1987. I believe you stated it a moment ago, Dr. Rodericks, that you believe those recommendations are just as good today and really there is probably no difference between what you recommended then and what we are talking about in track II today, technically speaking. But we all know the difficulty we have had and the roadblocks that were thrown up to the recommendations that your committee made. And we have seen the failure of it. And the reason being is that our critics seem to have more credibility than you do. Seem to.

And in the political world and in this modern communication world, perception is everything. It is a 30-second sound bite; it is a 20-second sound bite; it is a tragedy like occurred out in the Northwest that concerns us all—it is painful when these things happen.

So we know—and you have stated—that it is not an exact science. And no matter how perfect we are, we are not going to—as Mr. Volkmer's questioning suggests—we are not going to eliminate all bacteria from our food supply and keep it that way until it reaches the stomach of all our children. It is not possible today.

Now, perhaps somewhere out there, 10, 20, 30, or 40 years from now, it will be; but it is not in the foreseeable future. So that is the way in which I am asking the question, Dr. Cassens?

Dr. CASSENS. I will attempt to respond. And you have said exactly what I have been thinking.

I think it only makes sense to get a number of legitimate organizations involved, because it is not an isolated kind of problem. I really think the greatest difficulty is the fact that our food has been tainted with suspect science, and there has been a group of people

that have been very effective in using science in a way that I think discredits it.

The scientists have, obviously, been at fault, too, I think, because they have not come forward and tried to tell the truth. And often that truth is not too exciting, and often that truth costs a lot of money.

Mr. STENHOLM. Dr. Rodericks.

Mr. RODERICKS. I just had one comment from, perhaps, the larger perspective of risks to our daily lives from many, many different sources; that is how I spend my professional time.

This is just one of many kinds of threats to people's health. And one thing I think we have learned in the last 10 years is that there are many different—there are many criteria people, common people, use to judge risks that are very different from what technical experts like the four of us here judge risk.

We tend to see things more in terms of probabilities and how likely they are to occur. People's conceptions of risks and perceptions of risks are influenced by many other factors, whether it is a risk you take yourself or whether it is imposed, you see it as imposed on you by someone else. And I could list another dozen reasons why people's perceptions don't match the experts very well.

I think the only answer to this is the kind of education that these other panelists here this morning have emphasized so much and beginning at a very early stage to get people to understand that life is not risk free. But try to get some idea of the relative importance of different kinds of factors and how they affect their health is the best the technical experts can say.

Also, I think technical experts have to be much more honest about what we know and what we don't know and how far science can take us. It does not have all the answers now. And any expectations that we can immediately solve problems, if we just put scientific heads together, is just wrong. That is just not the way science works.

But we have to always show signs that we are making progress toward creating a safer food supply in this particular case. There has to be some evidence. And what I heard from critics, critics of our report, was not so much that what we were saying was incorrect but that the Government was not moving with great speed to implement every last suggestion we laid out.

There are all kinds of practical impediments to that. But what I hear is not so much the goal as a risk-free environment, as a risk-free food supply. I have not heard that from critics. But there has to be visible evidence of progress.

I heard from Dr. Cross this morning things that sounded very good to me in that regard.

Mr. STENHOLM. Any significance to questioning that I had of CDC in which, out of a $1.7 billion budget, the Centers for Disease Control has $3.3 million allocated to food-borne illnesses?

That doesn't necessarily mean anything to me or you, except perhaps this entire question of food-borne illnesses, along the lines of Mr. Volkmer's questioning today, is that really and truly most of it is in food preparation. And no matter how you cut it, the threat is food preparation and education rather than a major threat to so-

ciety as would be caused by other diseases, whether they be foodborne or elsewhere.

Am I off base in that rationale? Or if you don't have any comment, I don't ask you to make any.

Mr. DENTON. I would say that I think that you are probably right, not having access to exactly the same set of information that you do as far as the budget is concerned. But what it appears to be is they have been prioritized from the standpoint of having some other areas that they put greater emphasis on.

Mr. STENHOLM. That is my conclusion. And we are going to see a lot more emphasis on prioritization within this committee. And it is something that we will have to decide which is the higher priority and which is the lower.

Final question for you: Any thoughts concerning the process that we should go through—"we" meaning this committee and the Department—in, once again, pursuing the recommendations, Dr. Rodericks, that you started with your committee, that Dr. Cross is now saying that he is prepared to go full board on, and that we are prepared to be as helpful and cooperative as we can in committee?

We have had suggestions of a blue ribbon commission; we have had suggestions of a think-tank approach in which we get all of the players together and find out as many things as we can that we agree on and that we disagree on as a starter.

Any thoughts about some do's and don'ts to how we proceed from this point forward? Dr. Denton.

Mr. DENTON. As a general strategy, I think it is probably useful to think about it in the same terms that we have tried to in developing our educational model that we worked with with the six States that worked together on the food safety conference in September. There were four of them that we put together that represents about 17 different perspectives, if you will.

I think it is imperative that you have as many of the people that are involved in the actual day-to-day conduct of the food business. I think it is very important that you have the regulatory community involved in this process. I think it is very important that you have the research and education community involved in the process.

To effectively develop a strategy, everyone that has to work or has any contact in the work-a-day world of the food industry is going to be able to make very positive suggestions about how to go about this process.

It is not necessarily going to be easy to do. I also think that we probably need to include some consumer representation in this process.

Mr. STENHOLM. Dr. Rodericks, do you have a question? I want you to respond to one additional thought process. You were with the FDA.

Mr. RODERICKS. I was.

Mr. STENHOLM. The turf battles that we constantly have between the various administrative bureaucracies as well as the congressional bureaucracies, would you comment a little there along the same line of the question you were about to answer? And that is our last question.

Mr. RODERICKS. I tended to avoid turf battles myself. No, I certainly did see them go on.

Simplistically, at least, it seems to me we have a food safety system which is rather Balkanized. And I always thought it made sense to see if there was a way to integrate the food safety programs of the U.S. Government more thoroughly, whether that means creating a single agency, I don't know. I have not looked at that administratively. But the agencies have a lot to learn from each other.

They do have very different histories, I must say, and ways of doing things. This kind of inspection program that exists at USDA has no precedent or any kind of similarity to anything that FDA does in the way it goes about its inspection process. So there is some value in each kind, but how do you bring them together? I am not sure. But someone should really look at that.

The same thing when you get into chemical areas, there is the whole pesticide issue. Of course I know that is outside the bounds here, but that is an EPA matter that further complicates the food safety issue because of its separation.

Mr. STENHOLM. Gentlemen, thank you very much. We appreciate your testimony today. Again, we appreciate your past work as well and look forward to working with you in the future as we try to bring about a resolution to taking the best system in the world and making it better.

Thank you very much.

[Whereupon, at 1:15 p.m., the subcommittees were adjourned, to reconvene, subject to the call of the respective Chairs.]

[Material submitted for inclusion in the record follows:]

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

STATEMENT OF
DR. H. RUSSELL CROSS
ADMINISTRATOR
FOOD SAFETY AND INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE

BEFORE THE
SUBCOMMITTEE ON LIVESTOCK
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION
HOUSE COMMITTEE ON AGRICULTURE
U.S. HOUSE OF REPRESENTATIVES

MARCH 16, 1993

Mr. Chairmen and members of the subcommittees, it is a pleasure to appear before you to discuss our thoughts on the modernization of meat and poultry inspection. We appreciate your interest in improving our current program, and hope we can gain your support as we begin a revolutionary program to modernize the meat and poultry inspection program. As always, your advice and comments will be appreciated as we move forward.

The past year was a year of assessment and planning at the Food Safety and Inspection Service (FSIS). During 1992, FSIS took a good, hard look at where we have been -- all the way back to the inception of inspection. And we have positioned ourselves to make some tough decisions about where the Agency will go as we approach the 21st century. We must take FSIS from the organoleptic inspection system that has evolved since 1906 to a science and risk-based system.

Today, I will discuss a number of our new initiatives, including:

-- consumer-oriented proposals, such as mandating safe handling and cooking instructions for labels on all raw meat and poultry products;

-- technological innovations such as rapid inplant detection methods and organic-acid sprays that reduce pathogen loads; and,

-- stronger requirements for the industry to follow in producing products such as ground meat as well as tougher enforcement by FSIS of existing food safety standards.

Our agency is involved in a number of simultaneous activities. For instance, in January, as part of our ongoing strategic planning, we gave Secretary Espy our proposal for a new, two-track approach to the regulatory program of the future. Track I involves maximizing the performance of the current inspection system. Track II will be a totally new appróach to regulation in the future.

Shortly after we proposed this two-track strategy, we were faced with a food safety crisis -- the outbreak of E. coli 0157:H7 in Washington State. This crisis does not change our strategy -- our two-track system remains in place. However, we recognized that we needed to zero in on the pathogen-control aspects of that two-track strategy.

We are fortunate to have a new Secretary in place who has demonstrated his commitment to improving food safety. As soon as he learned of the outbreak of E. coli 0157:H7 in Washington State, he contacted the President and a Presidential Mission was formed to go to Washington State to visit with affected families and to testify before the Washington State Senate. With the Secretary's support, we are well-equipped to work now and to work quickly to improve our programs.

We have developed and presented to Secretary Espy a Pathogen Reduction Program (PRP) to ensure that our pathogen reduction goals receive the attention and resources they deserve. The PRP is a key part of Track I and overlaps into Track II.

Today, I would like to outline our two-track proposals as well as our PRP to show you where we are headed and how these programs fit together. I want to stress that these proposals are just that -- proposals. We will not implement these proposals for Track I, Track II or the PRP without input from all interested constituents, such as consumer groups, trade groups, scientific experts, our own employees, other Federal agencies, and Congress. We want to know what our constituents think about what we're proposing. If they don't like it, we want to know why and what they would suggest instead. I think the one thing I can safely say is that we all agree there must be changes. Finding and implementing the best course -- for now and the future -- is not something we can do alone.

Maximizing the Performance of the Current Inspection System (Track I)

As I mentioned, in early January, we proposed a two-track system approach to planning for the future. Track I focuses on our current meat and poultry inspection system. We cannot simply plan for the future and disregard needed changes we can implement right now.

Our planning on Track I is now centered around six elements, but we believe that a broadly-based approach may generate even more ideas.

Public Ownership

The first element is public ownership. Public ownership means actively involving all our constituents -- consumers, the industry, scientists, other Federal agencies, and our own workforce -- in an open, participatory decision-making process.

For instance, we plan to make scientific and policy papers available before -- not after -- programs are developed. We sincerely want review, comments, suggestions and criticisms by outside experts, employees and public interest groups.

We are planning to seek out public comment on our strategic plans through regional hearings scheduled for this spring. These hearings are tentatively scheduled to begin in Washington, D.C., in April, and will be held in several other cities across the United States. We will be actively seeking grass roots information and reactions.

Staff and Structure the Agency

A second way that FSIS will maximize the current program will be to ensure that Agency staff and structure are aligned so they can be fully utilized. Our current program is resource intensive. Eighty percent of our budget goes to pay for inplant personnel, and we can not keep up with industry growth unless we take other measures.

I recognize there has been much discussion on whether or not we need the additional 160 inspectors President Clinton has proposed be funded in his Economic Stimulus package. With all the discussion that has recently focused on problems with pathogens inspectors can't see, we need to remember that our inspectors have numerous other assignments that protect consumers. They inspect animals before and after slaughter to detect disease. They monitor the plant's control programs and inspect facilities and equipment for sanitation before operations can begin.

Furthermore, our inspectors examine carcasses for visible contamination, including fecal matter and ingesta, which may carry bacteria. They also conduct on-site rapid testing for chemical residues and collect samples to send to the laboratory. In processing plants, inspectors ensure that proper refrigeration and cooking steps are followed and check such vital steps as thermal treatment to prevent botulism from canned foods.

The 160 inspection positions proposed by the President would help to meet the current legal requirements for inspection coverage. We cannot just abruptly stop operating our current inspection system because we know it must be improved. Perhaps radical changes will be developed over the next several years. But in the meantime, we have to be sure the current system does what it can do well.

Labor Relations

A third important component of Track I is Labor Relations. It is imperative for FSIS to build a strong and mutually supportive relationship with employee organizations.

One of our first priorities in this area is to resolve questions about a Relations by Objectives activity FSIS managers conducted with the inspectors' union. We have also established and will continue to support the efforts of a Trust-building Committee and an Internal Communications Committee. Additionally, we are providing opportunities for more employees at all levels throughout the Agency to become involved in major initiatives from the beginning.

We recognize that employees who are stationed in plants have practical knowledge of how our programs work or don't work. We are committed to the principles of Total Quality Management (TQM), and will ensure all our employees are given the opportunity to participate in making decisions about changes to our inspection program now and in the future.

Reduction of Pathogens

The centerpiece of our Track I proposals is our goal to reduce pathogens. We have already begun our nationwide study to determine the microbiological baseline of the nation's meat and poultry supply. These baseline studies will be the "yardstick" by which we assess progress in our "war on pathogens." These data will tell us whether future prevention and inspection systems can reduce microbiological contamination.

Another feature of our goal to reduce pathogens is our encouragement to industry in the voluntary use of prevention systems. In 1992, FSIS took action in three areas as examples of this. We approved the use of irradiation of poultry; we moved to allow the use of Trisodium Phosphate in poultry processing operations; and we approved the use of organic acid sprays on cattle and swine. If our baseline studies do not show sufficient progress in reducing pathogens, these voluntary systems may cease to be voluntary.

I will elaborate on a series of other activities when I discuss our Pathogen Reduction Program.

Consumer Service and Education

A fifth key component of Track I is Consumer Service. FSIS will intensify its health and education programs that positively influence food industry employee behavior to reduce foodborne illness. We also propose to expand our efforts to provide consumers with information on food handling and cooking practices. As one key tool, we are proposing to mandate safe-handling and cooking instructions on meat and poultry labels.

In addition, FSIS will continue to coordinate the dissemination of its food safety resource materials through state extension and educational programs. We also believe food safety should have a place in the curriculum of every elementary and secondary school in the country, and we will work to accomplish that goal.

Our education efforts will go beyond pathogens and include support of nutrition labeling, information on issues such as genetic engineering and other steps to promote consumer information. The Meat and Poultry Hotline plays a large role in disseminating information. It continues to serve as a vital link between the Agency and the consumer, taking in over 138,000 consumer calls last year.

Science and Technology

Science and Technology is element six for Track I planning. We will make decisions based on science when it is available, but we also cannot wait for all the i's to be dotted, or the t's to be crossed before we take advantage of new information.

First, we will continue to prepare a list of research and development priorities and encourage research in those areas. We will not develop these priorities in a vacuum. We will work closely with our counterparts in the Animal and Plant Health Inspection Service (APHIS), the Agricultural Research Service (ARS), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC) and other Federal agencies to make certain we are on target. We would also work closely with CDC to develop data to determine the relative risks of various pathogens.

Second, we will use risk analysis, which includes risk assessment, management, and communication. I am appointing a team charged with identifying and quantifying risks through structured risk assessment. With help from our advisory committees and others, we will develop quantitative risk analysis

models that will allow us to identify risks and provide the rationale for policy development and resource allocation. Detailed economic analyses will be an important element of our risk assessment.

Third, we will establish specific procedures for obtaining the advice of recognized experts on issues affecting the scientific and technical basis of our regulatory activities.

Other Elements of Track I

As we improve our current program, we will also get tougher on our enforcement of existing food safety standards in the establishments we inspect. As an example, we just began a special review of beef slaughter plants to identify, for appropriate corrective action, plants that may be failing to consistently produce clean, unadulterated products. We will not tolerate plant operations that present a threat to public health.

Plants identified as presenting public health "problems" will be subject to Progressive Enforcement Action or withdrawal of inspection. Until all problems are corrected, FSIS will take any action necessary to ensure that no adulterated products are being shipped.

We also propose to develop regulatory strategies to improve our programs for residue detection, disease diagnosis, labeling, and consumer fraud enforcement and the whole range of FSIS responsibilities that complement pathogen reduction plans.

The Regulatory Program for the Future (Track II)

In contrast to our evolutionary approach in Track I, we expect Track II to be revolutionary. If this proposal sounds vague, it's supposed to. It would be wrong for us to have too much of a preconceived notion about what this new regulatory program should be. We are recommending a no-holds-barred approach, to think unencumbered by the past, and to design the regulatory program we need for the year 2000. I want to emphasize that as we plan for the Track II, we intend to disregard current restraints, including budget and legislative authority. We believe the best strategy is to decide what works best and then decide what changes in resources and authority would be necessary to implement such a program. Of course, we do have a few general principles in mind to guide the development.

First, we know that any new system must be based on science and risk. All of the experts have told us this, and we know it ourselves. The optimal inspection system described by the

National Academy of Sciences in 1985 was a science-based, risk-based system.

Second, we know that the management systems of the future must be based on TQM principles. The employees who will operate the program of the future will be well trained, highly skilled and accustomed to concepts of continuous improvement, process analysis, customer satisfaction, and other quality components.

Third, we know that we cannot take forever to complete this process. The timetable must be realistic, but we can't wait 10 years, either. To develop a realistic timetable, we need to further define how the project will be conducted.

Our objectives are clear. We must provide a vision of a public health oriented, risk-based inspection program that is not constrained by the configuration of the current program. We also must identify what would be needed to support implementation of a new system of inspection, including program mechanisms, necessary changes in the law and resources, including people and money.

We plan to evaluate all elements of Track II to ensure they are cost-effective and place the least possible burden on the taxpayer. We also must identify what research and developmental work still needs to be done to make good choices among the many ways we could go. To ensure that the new inspection system is not constrained by the current configuration, we plan to include food safety experts and others from outside FSIS in the development of Track II.

As a starting point, we will host, in October, the International Symposium on Meat Hygiene (World Meat and Poultry Summit) at Texas A&M University. This symposium will include food safety inspection experts from 25 countries around the world. We want to hear how other countries manage the elements of their inspection programs -- particularly those involving microbiological pathogens.

Pathogen Reduction Program

As I mentioned, this two-track strategy was already in place when we were faced in January with the outbreak of E. coli 0157:H7. After this tragedy occurred, we worked closely with Secretary Espy to zero in more aggressively on the pathogen reduction aspects of our two-track system. That is why we have developed a separate pathogen reduction plan -- the PRP. Although this plan was developed separately, it fits quite well into both Track I and Track II since it makes maximum improvements in current inspection and positions FSIS for future changes.

Before I detail our PRP, I want to emphasize one point. A pathogen reduction plan is much broader than additional microbial testing. When a food poisoning outbreak occurs, one question we get from the public is why we don't routinely test for pathogenic microorganisms in raw products as part of our inspection program. I want to respond to that question.

First, there is no rapid test currently available for pathogens in raw meat and poultry. We are working with the scientific community to ensure that accurate tests that can be used in the field are developed quickly, but for now, all we have available to us is laboratory testing. And laboratory testing is slow. For example, it takes approximately six days to receive results from a laboratory test for E. coli 0157:H7. It's simply not feasible to test and hold every carcass until laboratory results are obtained.

Second, a pathogen reduction program must be much broader than testing carcasses for bacteria. Emphasis must be placed on prevention. It is not efficient or effective to try to catch problems after they happen. An effective pathogen reduction strategy must focus on preventing contamination in the first place and making certain the prevention process is under control.

Third, we do not have enough information about human infective doses to set meaningful standards for microbial contamination on raw products at this time. Epidemiological reports show a large variability in susceptibility of patients due to age, sex, health status and a variety of known and unknown factors. We hope to have more information on this in the future, but right now, we just don't know enough to set specific numbers. Our best strategy at this time is to get the level of microbial pathogens as low as possible by addressing each point in the production process, from farm to table.

Finally, the costs associated with microbial testing of products would be prohibitive. The CDC has identified 10 bacterial agents of public health concern associated with meat and poultry products. Government costs for testing just 20 percent of every livestock or poultry carcass for the presence of each of the major pathogens could range as high as $58 billion per year. Even if this testing were feasible, the levels of bacteria on carcasses are not reliable predictors of the safety of finished products, since there are many possible points in processing, storage and distribution in which contamination can occur.

This does not mean we will never do routine microbiological testing as part of our meat and poultry inspection program. No one should doubt that we're moving in that direction. I agree with our critics that FSIS probably should be farther along with this type of testing by now. But we're not. Through our PRP, I

intend to do something about that now, instead of focusing on why we didn't do something in the past.

With that said, I will describe our Pathogen Reduction Program.

In recent years, FSIS has been laying the groundwork for a future inspection system that will:

- be based on the most up-to-date scientific knowledge and methods;

- employ criteria derived from quantitative risk assessments and epidemiological and microbiological surveys;

- focus on enhanced public health protection at critical points from the farm to the dinner table;

— incorporate the latest rapid detection and screening methodologies;

— use animal identification and traceback methods to determine the sources of potential or actual infections.

An integral feature of the future inspection system will be a Pathogen Reduction Program to reduce the likelihood that harmful microorganisms -- such as Salmonella, Listeria monocytogenes, or E. coli 0157:H7 -- will enter the food supply at key points in the production, distribution, and consumption chain. The plan the Department is now proposing is based on HACCP principles and incorporates the essential elements of a pathogen reduction approach. This includes critical "pre-harvest" production activities, research on rapid detection methods, "post-harvest" research, in slaughter and processing plants, food service and retail activities, and even more aggressive consumer education than has been undertaken in the past.

Additional actions will include such innovations as the use of organic-acid carcass sprays that reduce pathogen loads and rapid inplant detection methods or microbiological monitoring. Meat and poultry inspectors will eventually be equipped with microbiological swab kits or other tools to enhance the work they already perform to ensure that facilities and equipment are sanitary. Meanwhile, FSIS will carry out microbiological monitoring using existing methods.

In pursuing its new strategy, USDA will be making a decisive break with the past. Under Secretary Espy's direction, the Department will not wait for an outbreak of illness to alert us that a pathogen has become a problem. Nor will we be satisfied

with holding the line against contamination. USDA will strive to reduce contamination at the source.

The PRP incorporates actions that can be taken immediately at key points along the route from the farm to the table. Other preventive activities, such as those based on epidemiological information from the CDC, will be integrated into the program as the need for them is identified.

Some improvements will be difficult. But USDA believes that the people of this country want and deserve an up-to-date inspection system that is focused on protection from foodborne disease and is the most efficient use of taxpayers' dollars. The time is ripe for a comprehensive, cooperative effort engaging USDA and other government agencies, Congress, consumers, the scientific community, and the meat and poultry industry.

Allow me to address the proposed plan in more detail.

I. Pre-Harvest Production Activities

Pathogens that get into the food supply and make people sick may originate in the animals from which food is made. In the case of the recent epidemic in several Western states, it is possible that certain cattle brought to slaughter carried the E. coli O157:H7 organism in their bodies.

Unfortunately scientists do not know with certainty which animals are most likely to be harboring the organism or why they may be affected: it could be because of certain husbandry practices of the farmer; it could be because of the geographic location of the farm or its proximity to wild animal populations; it could be because the animals are old or stressed, or many other factors. Because scientists cannot tell us with precision where and why the organism appears, it has not been possible to design on-farm programs which will assist producers in making sure that their animals are not the source of these dangerous bacteria.

The pre-harvest production activities that are part of the PRP are designed to obtain answers to the underlying scientific questions, and use those answers in conjunction with basic animal identification information to build a better pathogen prevention system for animals destined for food.

Pre-harvest proposals include:

On-farm investigations: In conjunction with APHIS and ARS, we propose to conduct on-farm epidemiologic studies of foodborne enteric bacterial pathogens, using E. coli O157:H7 as a model to determine the characteristics and risk factors associated with infected animals.

Animal ID and traceback: We are proposing to design programs, secure necessary legal authority and put in place mandatory requirements for animal identification so that meat-borne problems can be traced back to their on-farm origins. Such requirements are the basis for effective pathogen controls and are also the foundation of prevention programs that are beneficial to both producers and their customers.

Pathogen prevention programs: We propose the development of a program designed to assist producers to eradicate or control disease organisms of public health concern. Models would be developed based on experience of other countries such as Sweden and Denmark as well as outcomes of U.S. on-farm investigations combined with resources from producer groups and assistance providers like APHIS, Extension Service (ES), the American Veterinary Medical Association, and universities.

II. Rapid Methods Development

Reducing pathogens that may get into the food supply depends on being able to detect their presence at various points in the food production process. We need methods to detect these microorganisms in live animals, on carcasses of animals in the slaughtering plant, on machinery or tables in the processing plant, in raw materials being used to make meat food products, and on the hands and clothing of workers and in finished products. Identifying these organisms requires sophisticated analytic methods to be used in differing and difficult circumstances, often by persons without extensive training. The methods development research part of this program is designed to accelerate the provision of these critically important tools.

Emphasis would be placed on new technologies (especially new advances in the fields of molecular biology, bioluminescence, and biosensing) to detect and enumerate the low numbers of human pathogens found in and on food products, the development of more rapid tests with shortened turn-around-times, and the development of simple to use, in-plant tests. New methods are needed by inspectors to detect temperature-abused products, to estimate microbial bioburden at various stages of processing, and to determine microbial pathogen contamination at selected Critical Control Points (CCP).

This area includes:

Methods development research: We propose to develop and evaluate methods for the detection and enumeration of microorganisms of public health concern in raw and ready-to-eat meat and poultry products and for implementation at Critical Control Points to monitor process control.

III. Post-Harvest Activities

During the time that animals are being slaughtered and processed, pathogens originating in the animal or from the environment may be transferred into the food. Under certain time and temperature conditions that are typical of food processing, bacteria may attach themselves to products and grow. Post-harvest activities are designed to investigate what happens to bacteria during all phases of food processing and design, and test interventions that break up the chain of bacterial contamination. HACCP programs for meat and poultry slaughter plants would be designed and pilot tested.

The post-harvest activities would include:

Slaughter and processing pathogen research: We are proposing to identify critical issues and expand existing research programs in FSIS, ARS, the Cooperative State Research Service, industry, and academic consortia to elicit further knowledge about the presence and persistence of foodborne pathogens during meat and poultry production and potential interventions aimed at reducing contamination.

Irradiation research: We propose to give immediate priority to research to support a petition to extend FDA approval for irradiation of fresh and frozen poultry to include red meat.

IV. Risk Analysis

Once data and information are gathered on pathogens in meat and poultry and proposed interventions are promoted to help reduce their prevalence, a sound scientific and economic process is needed to assess the inherent riskiness of the current procedures in terms of the potential for foodborne illness, and the value, in these same terms, of any interventions. Quantitative Risk Assessment (QRA) provides the tools to improve the soundness of agency decisions in protecting the public health by allowing for a logical, orderly assessment of risks and numerically estimating the potential for foodborne illness in old and new systems.

Included in this area is:

Quantitative Risk Assessment: We propose to adapt the science of quantitative risk assessment to foodborne hazards, especially of microbial origin, and to FSIS inspection activities, thereby improving Agency decision-making.

V. Slaughter Plant Activities

Even though all critical research questions have not yet been answered, FSIS recognizes and accepts its obligation to proceed with activities that are likely to succeed based on current theories about pathogen control. The agency also has the opportunity to introduce useful microbial detection technologies into the present inspection program as they become available, not waiting for the fully developed new system.

The PRP includes several activities that are based on present knowledge, especially that which suggests that pathogen presence on carcasses is likely associated with fecal contamination; that careful sanitation can reduce potential for cross-contamination; that HACCP principles have high potential for benefits; and that more information about microbiological profiles of species and classes of animals brought to slaughter will provide better opportunities for fine-tuning interventions.

The PRP also proposes to quickly include microbial monitoring techniques in the present inspection system, thereby empowering inspectors with significantly better tools to do their jobs.

Under slaughter plant activities, we propose to:

Expand micrbbiological baseline: We propose the design of national monitoring programs for cows, poultry, and swine. This program would provide a microbiological profile of these classes of animals; it will survey for bacteria of public health concern, i.e., E. coli O157:H7, Salmonella, Listeria monocytogenes, Clostridium perfringens, Campylobacter jejuni/coli, and staphylococcus aureus. Data generated by the baseline studies will show an "average microbial profile" for the class of animal studied. Plants that consistently produce products outside of this average can be identified and their slaughter operations reviewed and corrective action taken.

A baseline study is proposed for design and implementation to determine a microbial profile of ground beef. Three thousand samples would be collected and analyzed for indicator organisms and selected pathogens, including E. coli O157:H7.

Test "disabled" cows: We propose to determine the prevalence of fecal carriage of disabled cows compared to normal cows to assess the effects of stress on the shedding of bacteria causing foodborne human illness, i.e., E. coli O157:H7, Salmonella, and Campylobacter jejuni/coli. The study would determine if disabled cows constitute a greater public health risk than normal cows. This case control study has been designed to initially evaluate 500 disabled cows and 500 control animals.

Improve current slaughter procedures: We propose to review and modify current methods to maximize reduction of carcass contamination and prevent bacteria proliferation.

Enhance veterinary coverage: We propose to enhance effective use of Veterinary Medical Officers (VMO) in plants that slaughter high risk animals.

Mandate record-keeping: We propose to strengthen requirements for maintaining records of purchase and sale transactions, and in processing plants requirements for product formulation records. The focus would be on records that would facilitate identification and traceback.

HACCP micro monitoring: Based on current knowledge and work of the National Advisory Committee Microbiological Criteria for Foods (NACMCF), we propose to develop a microbiologic monitoring program for beef slaughter and pilot test in five representative beef slaughter plants to target CCP's that have been identified as microbiologically important. This could lead to the implementation of HACCP sampling in targeted beef slaughter plants.

VI. Processing Plant Activities

Processing plant environments also offer opportunities to intervene at critical control points to reduce pathogen presence. Again, the present PRP will take advantage of best available thinking and technology to minimize the chance of contamination reaching consumers of meat and poultry products. HACCP programs for meat and poultry processing plants need to be designed and implemented. Wherever current measurement technology permits microbial monitoring of critical control points, FSIS will build such techniques into its existing inspection framework. This would permit the immediate use of technical advancements by FSIS inspectors, and would encourage such use by the regulated industry.

Under processing plant activities, we propose to:

Control bacterial proliferation: We propose imposing time and temperature controls on various stages of processing, especially of ground meat products.

Improve current processing procedures: We would strengthen existing procedures designed to control bacterial proliferation.

Finalize "patty" docket and controls on similar products: We would propose regulations to specify cooking requirements for patties and like products.

Mandate safe-handling labels: We propose to mandate safe handling and cooking instructions for labels on all raw meat and poultry products and issue interim instructions for approving voluntary use of such statements on labels. A regulation is already under development. We also would provide for safe handling inserts and prominent cooking instructions on labels of school commodity products and National School Lunch Program purchases. A thorough cost-benefit analysis of this, and all other regulatory proposals, would be completed.

HACCP micro monitoring: Based on current knowledge and work of the NACMCF and the FSIS Ground Beef Workshop, we propose to develop a microbiological monitoring program. We plan to conduct pilot tests in five representative ground beef processing plants to target CCP's that have been identified as microbiologically important. This would lead to the implementation of HACCP sampling in beef processing plants.

VII. Food Service and Retail Activities

While pathogen reduction is the central goal of this effort, it is unlikely that it can ensure pathogen-free raw meat and poultry products in the near future. This means that those who further prepare and serve food will need to remain critically attentive and expertly equipped to perform their important preparation and handling functions. The PRP includes food service and retail activities that encourage providing these workers with scientifically up-to-date information and guidance, clear consistent instructions about how to do their jobs well and recognition that communication and coordination among Federal, state and local regulators is essential to an effective system.

Activities would include the following:

Sponsor teleconference: We propose to provide state and local public health authorities with current information on food safety requirements and methods of enforcement through a teleconference with these authorities.

Assist state enforcement programs: We would provide technical and resource assistance to states to carry out their enforcement efforts in food service and retail establishments. We would cooperate in developing and supporting model food codes to provide uniform technical guidance for cooking and handling.

Educate food handlers: We would work cooperatively with FDA, the Extension Service, and trade and professional organizations to identify the level of knowledge of food service workers in safe food handling practices and to identify existing food safety education materials and vehicles. We plan to determine which needs are not being met and develop an integrated and targeted education program for food service employees,

including day care centers, nursing homes, hospitals, restaurants and similar institutions, to teach proper cooking and handling of food.

Educate fast food chain employees: We propose to call upon corporate leaders of restaurants to ensure that their food service employees are instructed in safe food handling practices. We would prepare a joint HHS/USDA initiative to educate all restaurant managers and staff.

VIII. Consumer Awareness

As long as meat and poultry products are prepared by consumers, those consumers remain critical in terms of ensuring their own safety. Proper handling, storage and preparation of these perishable products is less widely known in contemporary households than it once was, and less time and attention are often devoted to these matters. The PRP includes activities that continue the agency's traditional recognition of the important role of consumer education and awareness in protecting public health.

Consumer education activities would include the following:

Intensify consumer awareness campaign: We propose to intensify our ongoing national consumer awareness campaign to improve the understanding of the risks of unsafe food handling practices, using ground beef safety as a key. We intend to positively influence consumer food buying and food handling behavior. We will evaluate the effectiveness of the campaign, using traditional and innovative measures.

Expand food safety education: We would increase cooperative efforts with agencies and organizations who share roles as food safety educators.

Upcoming Activities

Certainly, each of these initiatives -- Track I, Track II, and the PRP, have individual timelines we will follow to ensure our goals are met. I want to emphasize, however, that we are moving rapidly.

As I mentioned earlier, we are planning a series of public hearings to begin in April to get public participation and comment on our two-track system. We will contact a wide variety of industry and public interest groups and maintain a dialogue with Congress to ensure that all of the Agency's constituencies are aware of this and other opportunities to help plan the meat and poultry inspection program of the future.

After we have assembled information from the field hearings, we will host in October the International Symposium on Meat Hygiene at Texas A&M University (World Meat and Poultry Safety Summit). This symposium, which is held every four years, is an excellent opportunity for food safety experts from all around the world to share information on ways to improve the safety of meat and poultry products. Hopefully, we can borrow the best elements of all the current programs in place as we plan our future program. For instance, over the past several years, the Netherlands, Sweden, and Denmark have instituted a number of changes in their inspection programs to reduce microbial pathogens. We expect that much of their research will be applicable to the U.S. meat and poultry inspection system.

I hope this discussion of our two-track approach for planning and the PRP provides a clear view of where FSIS is headed. We believe they form a cohesive strategy to meet the need for a modern, public-health oriented meat and poultry system of the future.

As I said at the outset, we want these proposals to be considered in an open, interactive process. We want to involve as many of our constituencies as possible and solicit as many expert opinions as possible.

We also plan to interact extensively with public health experts. For instance, during the E. coli outbreak, we worked closely with the CDC, and we want that interaction to continue. Many of our plans will involve the FDA and other Federal agencies. Not only do we recognize the value of consistent policies emerging from the various Federal agencies, but we recognize the value of soliciting as many expert opinions as possible.

Mr. Chairmen and members of the subcommittees, this concludes my statement. I will be happy to answer any questions you might have.

(Attachment follows:)

Food Safety and Inspection Service

Pathogen Reduction Program

The War on Pathogens

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PATHOGEN REDUCTION PROGRAM: OVERVIEW

The USDA's FSIS is taking immediate steps to strengthen public health protection by squarely facing the risks posed by microbial pathogens in the food supply. These actions will be coordinated in a program that will in effect be a "war on pathogens."

The control of pathogenic microorganisms is and always has been an implicit goal of the Federal meat and poultry inspection program. The program has worked to achieve this goal through such activities as continuous organoleptic inspection in slaughterhouses, the daily monitoring of operations in further processing plants, laboratory analyses and scientific research, and consumer education.

In recent years, USDA's FSIS has been laying the groundwork for a future inspection system that will:

- be based on the most up-to-date scientific knowledge and methods;
- employ criteria derived from quantitative risk assessments and epidemiological and microbiological surveys;
- focus on enhanced public health protection at critical points from the farm to the dinner table HACCP;
- incorporate the latest rapid detection and screening methodologies;
- use animal identification and traceback methods to determine the sources of potential or actual infections.

An integral feature of the future inspection system will be a Pathogen Reduction Program to reduce the likelihood that harmful microorganisms--such as Salmonella, Listeria monocytogenes, or E. coli O157:H7--will enter the food supply at key points in the production, distribution, and consumption chain. The plan the Department is now adopting is based on HACCP principles and incorporates the essential elements of a pathogen reduction approach. This includes critical "pre-harvest" production activities, research on rapid detection methods, "post-harvest" research, in slaughter and processing plants, food service and retail activities, and even more aggressive consumer education than has been undertaken in the past.

Additional actions will include such innovations as pre-evisceration organic-acid carcass sprays and rapid inplant detection methods or microbiological monitoring. Meat and poultry inspectors can and will eventually be equipped with microbiological swab kits or other tools to enhance the work they already perform to ensure that facilities and equipment are sanitary. Meanwhile, FSIS will carry out microbiological monitoring using existing methods.

In pursuing its new strategy, USDA will be making a decisive break with the past. In the future, the Department will not wait for the pathogens to become a problem. Nor will it be satisfied with holding the line against contamination;. USDA will strive to reduce contamination at the source. Department personnel will not just stand at their positions inside official establishments or within the bounds of bureaucratic turf. They will be going out into the fields among the herds and flocks to find the places where pathogens lodge so as to be better prepared to enumerate and eliminate them.

Thus, under the rubric of "pre-harvest production activities," FSIS, working with Animal and Plant Health Inspection Service (APHIS) and other Government agencies, will carry out on-farm investigations and epidemiological studies of foodborne enteric pathogens. Although USDA intends eventually to deal with all serious pathogens through detection and eradication, it is beginning this effort -- appropriately--with a study of E. coli O157:H7 characteristics and risk factors in cattle herds. The Department is also seeking legislative changes to mandate animal identification and traceback in order to determine the herds of origin of infected animals arriving at the slaughterhouse. Further, to be truly proactive, USDA will be developing pathogen prevention programs to help producers keep their livestock from becoming carriers of dangerous bacteria. The resources of Government agencies and professional associations will be marshalled in this effort.

USDA agencies will speed the development of new methods—especially rugged, reliable tests that can yield results quickly—and make them available to inplant inspectors. Efforts are now underway to apply new advances in molecular biology, bioluminescence, and biosensors that are capable of detecting low numbers of disease-causing bacteria on food products. Even in highly technical areas it will not be business as usual. FSIS intends to seek authority to conduct and fund its applied research, especially in the areas of rapid tests and post-harvest pathogen control.

In the slaughter plant environment, FSIS still lacks the quantitative data that would permit it to measure such reduction. However, already underway is a microbiological baseline study that covers steers and heifers—the chief sources of the steaks and roasts familiar to consumers. The baseline study will be expanded to include cows, chickens, and pigs.

More must be learned about the health of cows coming to slaughter, including information on the public health significance of stressed or disabled cows compared with that of normal or healthy cows. Questions about the relative prevalence of disease-causing bacteria in these cattle populations must also be answered.

In the area of further processing, FSIS will seek to establish stricter requirements for boneless beef reinspection by establishments and for the conditions under which hamburger patties are processed commercially. The agency will also move to publish a final regulation establishing time and temperature minimums for the processing of partially cooked hamburger patties to prevent the recurrence of E. coli O157:H7 and other outbreaks in which such products have been implicated. USDA and FDA will strongly encourage preventive actions across the whole range of processed foods, and will recommend and support industry initiatives to establish certified HACCP programs. Inplant microbiological monitoring would be a key feature of such programs.

Finally, USDA is taking the initiative in strengthening protection at food service establishments and in the homes of consumers. For example, the Department is preparing to mandate the use of safe-handling labels on raw meat products sold at the food service and retail level, and the use of safe-handling inserts to accompany shipments of meat products used in such purchase programs as the National School Lunch program. USDA will also increase cooperative efforts with FDA and other agencies and organizations that share roles as food safety educators. Bold action can now be expected to convey food safety information to the general public.

The Pathogen Reduction Program incorporates actions that can be taken immediately at key points along the route from the farm to the table. Other preventive activities, such as those based on epidemiological information from the Centers for Disease Control and Prevention, will be integrated into the program as the need for them is identified.

Some improvements will be difficult and will have costs that exceed those of the current inspection program. But USDA believes that the people of this country want and deserve an up-to-date inspection system that is focused on protection from foodborne disease. The time is ripe for a comprehensive, cooperative effort engaging the Department, Congress, consumers, the scientific community, and the meat and poultry industry.

(The complete report is held in the committee files.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention - CDC
Atlanta GA 30333

Statement of

James M. Hughes, M.D.

Director

National Center for Infectious Diseases

Centers for Disease Control and Prevention

Public Health Service

Department of Health and Human Services

before the

Subcommittee on Department Operations and Nutrition

and

Subcommittee on Livestock

Committee on Agriculture

U.S. House of Representatives

March 16, 1993

I am James M. Hughes, M.D., Director, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). I am accompanied by Mitchell L. Cohen, M.D., Director, Division of Bacterial and Mycotic Diseases, NCID, CDC. We are pleased to respond to the Committee'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 by which CDC identifies foodborne hazards and characterizes 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. Although a foodborne illness can be brief and mild, it can also be life-threatening, causing miscarriage, hemolytic uremic syndrome, chronic kidney disease, arthritis, and death, as evidenced by the recent outbreak of disease caused by E. coli O157:H7 which contaminated hamburger. During the past 15 years we have learned a great deal about foodborne disease. For example, we have identified previously unrecognized bacteria such as Campylobacter, Listeria, and E. coli O157:H7 as important causes of foodborne disease. We also have recognized that bacteria such as Salmonella, which frequently contaminates meat and poultry, can be associated with nontraditional food vehicles such as tomatoes and melons. All of these data suggest that foodborne disease is an ever changing public health challenge--a problem of emerging infectious

disease. The recent Institute of Medicine (IOM) report, "Emerging Infections," identifies six factors which can lead to emerging microbial threats--changes in human demographics and behavior, technologic advances, economic development and land use, international travel and trade, microbial adaptation, and a breakdown of public health measures--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 tne IOM report for the record.

Meat and poultry products have been recognized as an important source of foodborne disease. These products become contaminated during slaughter and processing, and when they are undercooked or mishandled, can lead to disease. Prevention of meat- and poultry-borne disease requires a coordinated program of risk assessment and risk management. USDA's Food Safety Inspection Service (FSIS) has the legislative mandate to ensure that meat and poultry products are not adulterated or misbranded. The Food and Drug Administration (FDA), an HHS agency, shares authority with USDA to take action against adulterated or misbranded meat and poultry products in interstate commerce, outside of USDA inspected facilities. FDA also has regulatory authority over the remainder of the food supply. While CDC is not responsible for the regulation of food safety, as the Nation's Prevention Agency, we have the knowledge, skills, and perspective critical to a comprehensive, science-based program

for foodborne disease surveillance, outbreak investigation, diagnosis, and prevention.

CDC has expertise to define which microorganisms are serving as meat- and poultry-borne pathogens, to characterize epidemiologically and clinically the resulting illnesses, and to identify risk factors for infection. Thus, CDC's primary role in the coordinated federal program to prevent meat- and poultry-borne disease is that of risk assessment.

The tools CDC has developed are the Foodborne Disease Outbreak Surveillance System, intensive epidemiologic and laboratory investigations of foodborne disease outbreaks, surveys and studies of specific foodborne diseases, laboratory-based surveillance of specific foodborne microorganisms, and analysis of strains of foodborne microorganisms submitted to our reference diagnostic laboratories. I would like now to discuss each of these components in more detail.

1. **Foodborne Disease Outbreak Surveillance System**

The present system of foodborne disease outbreak surveillance began in 1966 when all reports of disease outbreaks attributed to food or water submitted to CDC by state and territorial health departments were incorporated into annual summaries. As currently conducted, foodborne surveillance comprises the collection, collation, and analysis of data on

foodborne disease outbreaks provided to us by state health departments and the dissemination of those data to appropriate individuals and organizations. In the past 10 years, approximately 5,000 foodborne outbreaks, involving 150,000 persons and 150 deaths have been reported to CDC. Analysis of these outbreaks has proven valuable in characterizing the risk of foodborne diseases and documenting the efficacy of regulatory controls developed in response to CDC recommendations. As an example, in 1979-1981, CDC investigated a series of Salmonella outbreaks traced to pre-cooked roast beef. After these investigations indicated that cooking times and temperatures were inadequate to kill Salmonella, the regulations were changed. Since then our surveillance data indicate that very few salmonellosis outbreaks are now traceable to pre-cooked roast beef.

2. Epidemic investigations

Another important source of epidemiologic data on epidemic foodborne disease is CDC's emergency response to foodborne disease outbreaks. The large outbreak of E. coli O157:H7 infections which occurred earlier this year in the western states represents a serious public health problem. In response to this outbreak, five CDC field teams with 14 medical and veterinary epidemiologists investigated the outbreak in collaboration with state and local public health officials. Information from the investigations has been shared with collaborators from local,

state, and federal agencies, including FSIS. These investigations traced infections to consumption of hamburger, which led to 1) a rapid product recall, limiting the size of the outbreak; 2) a change in cooking requirements for hamburgers; 3) identification of possible sources of implicated meat in order to change slaughter and processing practices that increase the risk of contamination; and 4) identification of factors which lead to person-to-person spread of infection in day care centers. E. coli O157:H7 was first identified as a foodborne pathogen during CDC investigations of hamburger-associated outbreaks in 1982, and much of what is known about this emerging public health threat has been learned during CDC's response to subsequent outbreaks.

The epidemiology of foodborne disease, however, is very complex. Although our current surveillance systems and epidemic investigations are critical to our understanding of foodborne disease and its control, these two sources of information focus only on foodborne disease outbreaks. However, most foodborne-related diseases occur as isolated or sporadic events rather than as part of dramatic outbreaks. The characteristics of these sporadic cases can be very different. These differences have important implications for the control of illness in humans. Human infections by Campylobacter jejuni provide a good example of this phenomenon.

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Campylobacter jejuni has accounted for 5% of foodborne disease outbreaks and 2.2% of outbreak-associated cases since we first received state reports in 1980. Between 1980 and 1987, a total of 53 outbreaks due to Campylobacter were reported; of the 37 with a specific food identified (or implicated), 17 (46%) were associated with raw milk. However, the cases of Campylobacter infections which are outbreak associated represent only a small percentage of the estimated 2 million cases that occur each year in the United States. In contrast to the outbreak data, studies by CDC and others suggest that poultry and not raw milk is the most common vehicle for the sporadic cases. In sporadic cases of Campylobacter jejuni infections occurring among members of a health maintenance organization in Seattle, at least 50% were accounted for by poultry, including chicken, turkey, and cornish game hens. Among university students in Georgia, 70% of cases were associated with eating chicken, often undercooked or raw. As this example has shown, CDC needs to understand sporadic foodborne illnesses as well as outbreaks.

3. **Studies of specific foodborne diseases**

The epidemiology of sporadic foodborne disease is often defined by prospective studies. For example, after outbreak investigations demonstrated that epidemic listeriosis was caused by eating specific contaminated foods, studies were established by CDC to evaluate whether all cases of listeriosis were foodborne. These studies used patient interviews and

microbiologic investigations of foods in patient refrigerators, retail outlets, and factories to determine whether contaminated food was the source of all listeriosis cases. The patient interview studies found that eating soft cheeses, undercooked chicken or hot dogs, and food purchased from store delicatessens were associated with listeriosis. The microbiologic studies confirmed these findings in general, and in several instances provided definite proof of foodborne transmission of the microorganism. This was most clearly shown when 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, unopened packages at the plant, and the plant environment. These studies confirmed the foodborne nature of listeriosis, and led to specific recommendations for producers, consumers, and physicians for the prevention of this disease.

4. Laboratory-based surveillance for foodborne pathogens

CDC and State Public Health Departments have for many years used the public health laboratories to monitor specific foodborne microorganisms such as Salmonella. Isolates of Salmonella are submitted to state laboratories for serotyping, and the results are transmitted to CDC. These data have many uses, including identification of new strains of Salmonella introduced into food animals, and tracking the spread of epidemics. For example, our data demonstrate that the epidemic of Salmonella enteritidis

associated with eggs began in New England and has been increasingly reported from many other areas of the United States. In some parts of the country this type now constitutes more than a third of all Salmonella. Public health officials use these data to recommend prevention measures at the state and national level, and agriculture officials use them in educational programs for producers.

5. Analyzing isolates submitted for reference diagnostics

CDC has long maintained expertise in the identification and characterization of foodborne microorganisms submitted to its reference laboratories. For example, when the problem of egg-associated Salmonella enteritidis infections was identified as a major threat to public health, we applied a variety of methods of subtyping to strains of S. enteritidis in our reference laboratories, and determined that a technique known as phage typing was the best available method. With the support of the FDA and USDA, phage typing has been used to demonstrate that infected chickens on the farm are the source of contamination of eggs. Developing new and improved subtyping methods is an ongoing activity at CDC. CDC laboratories have also developed new subtyping schemes for E. coli O157:H7 which have been instrumental in tracking the recent epidemic strain in meat and affected persons. This technique has been vital in defining the scope and source of the outbreak.

Despite this impressive record of achievement, continuing hazards in our food supply tell us that we must do better. We have identified four activities that will lead to better control of foodborne disease.

1. **Closer coordination with risk management agencies**

CDC responds rapidly to requests from state epidemiologists for collaboration and leadership in investigating epidemics of foodborne disease. Through collaboration with the FDA and USDA's Food Safety Inspection Service (FSIS), outbreak investigations frequently identify possible points of entry of pathogens into the food supply. USDA's Animal and Plant Health Inspection Service (APHIS) veterinary epidemiologists assigned to CDC have augmented CDC's ability to extend epidemiologic investigations into livestock and poultry production, and have improved collaboration and communication between CDC and APHIS. Further collaboration with USDA/FSIS personnel will similarly augment our ability to investigate the slaughter and processing environment. Epidemiologic studies of the food chain conducted in conjunction with outbreak investigations are important sources of information for refining Hazard Analysis Critical Control Point (HACCP) operations. HACCP is an accepted method of identifying points of entry and control of foodborne pathogens.

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

Effective surveillance is key to identifying and tracking the prevalence of foodborne diseases. Such surveillance provides policy makers and health professionals with the basis for developing, implementing, and evaluating control policies. We are developing electronic surveillance systems that will make reporting from state health departments to CDC more rapid, easier, and, hopefully, more complete to strengthen our stand against recognized and emerging foodborne pathogens.

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

Rapid and effective reaction to foodborne disease requires a nationwide system in which public health laboratories in all states identify potential foodborne pathogens, electronically transmit the information to CDC for cluster analysis and interpretation, and rapidly relay appropriate microbial isolates to CDC for molecular epidemiologic studies. CDC has developed a computer-based data management and reporting system (the Public Health Laboratory Information System), and is in the process of installing this system in all public health laboratories. We are also developing software modules for the foodborne pathogens of interest. CDC is expanding and improving pathogen subtyping systems which give CDC important information regarding strain differences in foodborne pathogens. Such systems will help refine CDC's ability to identify case clusters and unusual

events. Laboratory and human resource needs in state public health laboratories must also be addressed.

4. Proactive foodborne disease prevention programs

Proactive foodborne disease prevention programs for recognized hazards require quantitative risk assessment and development of Hazard Analysis Critical Control Point plans for all foods and menu items. In the short term, an effective prevention effort would include a program of geographically and demographically representative sites for intensive surveillance and investigation of acute human illness due to currently recognized high priority bacterial foodborne pathogens. Food microbiologic assessment coordinated with these efforts and foodborne disease outbreak investigations will generate data useful in the dose-response and exposure assessment phases of risk assessment. Collaborative investigations involving FDA, CDC, and state health departments on foodborne listeriosis, salmonellosis, campylobacteriosis, and Vibrio infections have provided knowledge and experience with active surveillance programs.

In the longer term, to more completely identify foodborne hazards, characterize their risk, and help set foodborne disease prevention priorities, an expanded active 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.

To conclude, CDC has an integral role to play, along with the FDA, the USDA and state and local authorities, in the collaborative response to food safety issues. Improving food safety and meeting emerging foodborne disease problems in the 21st century will require a comprehensive program that will conduct surveillance to 1) rapidly determine populations at highest risk for foodborne infections and severe outcomes, 2) further document the important causes of foodborne disease and identify new foodborne disease threats as they develop, and 3) more completely determine which products, processes, and practices lead to foodborne infections. Based on that information, effective educational programs for producers, processors, preparers, and consumers could be designed. Defining how foods become contaminated, developing rapid and accurate diagnostic tests for foodborne pathogens, and developing control strategies will minimize and prevent contamination of food by disease-producing microorganisms.

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

(Attachment follows:)

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
Division of International Health

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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.

(The complete report is held in the committee files.)

United States General Accounting Office

GAO

Testimony

Before the Subcommittees on Livestock and Department Operations and Nutrition, Committee on Agriculture, House of Representatives

For Release on Delivery Expected at 10:00 a.m. EST Tuesday March 16, 1993

FOOD SAFETY

Building a Scientific, Risk-Based Meat and Poultry Inspection System

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

GAO/T-RCED-93-22

Mr. Chairmen and Members of the Subcommittees:

We are pleased to be here to discuss the effectiveness of the federal meat and poultry inspection system and the need for changing to a scientific, risk-based system. Concerns about the adequacy of the U.S. inspection system have been heightened by recent deaths and illnesses in Washington and other western states attributed to undercooked hamburger patties contaminated with pathogenic bacteria. The public interest raised by this tragic incident provides another opportunity for the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) to make changes in the inspection system that are necessary to better protect public health.

In summary, although experts agree that the intensity and type of inspection coverage should be determined by the risk a particular food presents, the current meat and poultry inspection system is not based on risk and is not able to adequately protect the public from foodborne illness. Labor-intensive inspection procedures that rely on inspectors' sense of sight, smell, and touch, drain resources that could be put to better use in a risk-based system. While inspectors may identify some contamination using the traditional methods, they cannot see, smell, or feel microbial pathogens, which are widely regarded as the principal risk associated with meat and poultry. Furthermore, neither FSIS nor the industry is required to routinely test for such pathogens.

Although FSIS has recognized the need to modernize its inspection system since the late 1970s, it has made little progress. There has been no lack of good ideas on what needs to be done. Rather, FSIS has been hampered by the lack of a well-designed strategic plan, difficulties in achieving a consensus of all affected parties on which specific changes are necessary, and inflexible laws and regulations that lock the agency into the existing system.

Furthermore, we believe that any changes in the meat inspection system should occur within the context of the entire food safety system. In this regard, we reported in June 1992 that this entire food safety inspection system needs to be fundamentally restructured.[1] We found that the federal food safety inspection system is inconsistent, inefficient, and unable to adjust to changing public health risks. We recommended that a uniform, risk-based inspection system be established, preferably under the direction of a single agency.

Before providing more detail on our findings, let us briefly give you some background on the current inspection system.

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[1]Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992). See appendix I for a listing of GAO and other reports issued since 1977 on the federal food safety inspection system.

BACKGROUND

At the turn of the century, Upton Sinclair's The Jungle raised a public outcry about contagious animal diseases, unsanitary conditions, deceptive practices, and lax government inspection at meat packing plants. The Congress responded to this outcry by passing the Federal Meat Inspection Act in 1907. This act and a subsequent poultry act require federal inspection of meat and poultry to ensure that they are safe, wholesome, and correctly labeled and packaged.

These acts are aimed at keeping meat and poultry from diseased animals off the market and ensuring that slaughter and processing operations take place in sanitary conditions. To achieve these objectives, the acts require continuous inspection at the time of slaughter. Each individual animal carcass is examined by an on-line USDA inspector.[2] In 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.

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[2]In fiscal year 1991, FSIS inspectors visually checked about 81.3 million swine, 29.6 million cattle, 4.4 million sheep and lambs, 1.9 million other livestock, and 6.6 billion chickens and other birds.

After slaughter, meat and poultry from government-inspected carcasses can be inspected again during further processing. (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 daily by a USDA inspector, who may spend from 15 minutes to several hours performing various inspection duties. These inspections, too, rely primarily on organoleptic methods.

CURRENT INSPECTION PROGRAM HAS SIGNIFICANT LIMITATIONS

The current meat and poultry inspection system, like the overall food safety system, has not adequately responded to changes that have occurred in the kind of risks foods present. With advances in animal and veterinary science, many infectious diseases have been controlled. While the human health hazard posed by animal diseases has decreased, microbial hazards associated with the crowding of animals and other factors have grown. FSIS clearly recognized this change in risk in its 1991 report to the Congress. According to that report, microbial hazards present the greatest risks to public health posed by meat and poultry. Because the meat and poultry inspection system is not a scientific, risk-based system, it has not kept pace with these developments. As a result, the system is inadequate to protect consumers from today's most serious food safety risk--pathogenic microorganisms.

The current system suffers from at least four significant limitations. First, current laws restrict FSIS's flexibility in responding to changes in risk. Regardless of the risk to public health, FSIS is required by law to perform continuous inspection at slaughter plants--examining every carcass--and to visit each processing plant daily. Because of these requirements, the agency is limited in its ability to adjust inspection frequencies to respond to changing health risks. To illustrate the impact on resources of inspecting every carcass, let us describe the resources required to examine the 6.6 billion birds slaughtered in fiscal year 1991. At the fastest line speeds, an inspector has about 2 seconds to visually examine the inside and outside surfaces of each bird and feel the eviscerated internal organs. We calculate that over 1,700 inspectors are needed to carry out these inspections. Some experts have questioned the public health benefits of such an inspection procedure and the effectiveness of an inspector who examines 12,000 or more birds a day. Proposals have been made for slower line speeds to give inspectors more time to check each bird but increasing inspection time from 2 seconds to 4 seconds would require hiring another 1,700 inspectors.

Second, FSIS allocates considerable resources to activities not related to safety. FSIS estimates that it spends half of its resources on inspections related to quality, economic issues, and other non-safety related areas. Such an allocation appears out-of-line with FSIS's stated mission--ensuring safe and wholesome meat

and poultry. A 1991 FSIS management study found that emphasis on economic adulteration continued to dominate daily inspection time.

A third limitation is inconsistency. Over the years, requirements and ambiguities in the law and changes in the food industry have resulted in inconsistent decisions on what types of meat and poultry products are subject to FSIS inspection. As a result of these decisions, many food products that pose similar health risks to consumers are subject to significantly different inspection frequencies. For example, under the meat act FSIS is responsible for inspecting cattle, swine, goats, sheep, and horses, and inspectors must be continuously present during slaughter. In contrast, meat products under the Food and Drug Administration's jurisdiction, such as venison, buffalo, and rabbit, are not subject to such requirements. The Food and Drug Administration inspects plants producing these meats about once every 3 years.

Fourth and most important, FSIS does not routinely perform microbial tests of equipment surfaces or raw products. Nor does it require industry to perform such tests. Instead, FSIS relies on inspection methods that can not identify microbial pathogens, the most serious public health risk associated with meat and poultry. Inspection equipment we observed during visits to meat and poultry plants included knives, flashlights, mirrors, and thermometers, none of which can detect the most serious safety hazards. Some plants recognize the importance of microbial testing and have

established their own programs, even though they are not required to do so. For example, one plant we visited started a microbial testing program to check on the effectiveness of its cleaning procedures. Test results indicated that even though cleaned surfaces had passed FSIS inspection, some surfaces still contained high levels of bacteria. Company management therefore revised the cleaning procedures to reduce bacteria levels.

EFFORTS ARE NEEDED TO BUILD A MODERN INSPECTION SYSTEM

Good ideas have not been lacking on what needs to be done to improve the federal meat and poultry inspection system. Over the years many groups, including the National Academy of Sciences, USDA's Inspector General, and GAO have thoroughly studied the current inspection program, described its limitations in detail, and proposed, by our count, more than 200 recommendations for modernization. Philosophical differences exist on some points, such as how much of the inspection function can be turned over to industry. But there is general agreement that FSIS should be headed toward a risk-based inspection system based on modern science and technology.

To achieve the desired goal of a scientific, risk-based inspection system for meat and poultry, FSIS will need to (1) develop and implement a clear and detailed plan for change, (2) obtain a consensus for change by soliciting the involvement of all

interested parties, and (3) seek legislative changes to the meat and poultry inspection acts and congressional guidance on the objectives of the federal inspection system.

Developing a Plan for Change

In response to the tragic incident in the western states, where two children died and more than 450 individuals became ill from eating contaminated hamburgers, FSIS announced a two-track plan to update the meat and poultry inspection system. Track one, currently under development, is a near-term plan for maximizing the effectiveness of the existing system. Track two, not yet initiated, is described as a longer-term "revolutionary plan" aimed at overhauling the entire system.

We believe it is imperative that FSIS address the underlying problems of the current inspection system. For example, hiring 160 new inspectors, as FSIS has recently announced, will help alleviate the load on the existing system and to some extent may rebuild public confidence. But adding inspectors does little to address the underlying limitations of the current inspection system--inflexible inspection frequencies, questionable resource allocation, inconsistent treatment of products posing similar risks, and a lack of rapid analytical tools to identify microbial contamination. No matter how many thousands of FSIS inspectors are

assigned to slaughter lines or processing plants, they cannot visually detect pathogenic bacteria.

As FSIS develops its long-term plan to overhaul the entire system, it needs to research alternative inspection approaches, such as (1) thoroughly examining a statistical sample of carcasses to provide the desired degree of confidence instead of inspecting each carcass; (2) performing unannounced inspections of processing plants, basing the frequency of such inspections on risk, rather than inspecting each processor daily; and (3) using scientific methods to identify and control pathogenic bacteria instead of relying primarily on organoleptic inspection methods. FSIS's plan should set out specific goals, identify the barriers to meeting these goals, develop countermeasures to identified barriers, set milestones, and require periodic progress reports.

Obtaining Consensus

Even with a comprehensive plan, FSIS can not achieve success on its own. FSIS must also enlist the aid of all interested parties. Our discussions with representatives of the inspectors' union, consumer groups, industry, and FSIS indicated a lack of mutual trust and a reluctance to work together to ensure a safe and wholesome product to consumers. However, these representatives also stated that they were optimistic about the FSIS Administrator's efforts to develop a cooperative atmosphere by

improving communication and considering outside views in agency decisionmaking.

Recent failed attempts to improve the inspection system illustrate the need for consensus on major changes. Studies found that a streamlined inspection system for cattle--which attempted to shift certain quality-related inspection tasks to plant employees--when properly implemented was as effective as traditional inspection. However, criticism by the inspectors' union and consumer groups contributed to the system's termination. Similarly, the failure of discretionary inspection (a risk-based system that does not require daily inspection of processing plants) can be attributed in part to a lack of trust in FSIS management by industry, consumer groups, and the inspectors' union. Union representatives and consumer groups, in particular, said that FSIS did not make adequate efforts to elicit their support or clearly demonstrate that the proposed changes would benefit public health. In their view, FSIS made these changes to aid industry by reducing the level of inspection and increasing line speeds.

Even though the FSIS Administrator has emphasized that all constituent groups should participate in initiatives to change the inspection system, the agency is developing its current track-one plan without a formal mechanism to obtain outside views. At recent Senate hearings on the Washington state outbreak, a spokesperson for consumer groups expressed concern that in developing its

response to the incident, FSIS consulted with industry and not consumer groups. FSIS also decided not to release its plan until it was approved by the Secretary of Agriculture.

Seeking Legislative Change

We must not underestimate the magnitude of the effort to implement the organizational and scientific changes necessary to improve the inspection system. Modernizing a system that has survived largely unchanged for almost a century and forming a partnership among previously acrimonious parties will require strong leadership. Here, we believe the Congress can play an important role by providing the stimulus for change, strong support for agency management, and the vehicle for change through new legislation.

The basic criterion behind new food safety laws should be a scientific, risk-based system. That is, agency focus and resources should be directed towards reducing the most serious risks to public health. Since food safety risks change over time, FSIS needs the flexibility to adjust its inspection and research resources to target the most serious food safety risks.

FSIS could assist the Congress in its efforts by identifying and seeking the legislative changes that would provide the flexibility needed under a risk-based inspection system. For

example, FSIS could assess the public health benefits of and continued need for organoleptic examination of every carcass, as currently required by law. While careful organoleptic examination of some animals, such as old dairy cows, may still be needed, the benefit of such inspections for young, market animals that account for the vast majority of slaughtered animals is less certain.

FSIS could also seek a broadening of the meat and poultry acts' definition of adulteration. FSIS's Administrator has stated that under current law the presence of naturally occurring bacteria in raw meat and poultry does not constitute adulteration. Since microbial pathogens are the greatest health risk associated with meat and poultry, the Administrator could propose that the statutory definition of "adulterated" be amended to include pathogenic bacteria.

Our past work has shown that the inefficiencies and ineffectiveness of FSIS's meat and poultry inspection also apply to other food products and other federal inspection agencies. In our 1992 report, we discussed the results of our comprehensive review of federal food safety inspections and noted problems of inefficient resource use, inconsistent inspection of foods posing similar risks, and lack of coordination. We also expressed concerns about the overall ability of federal inspection agencies to ensure food safety. We believe that ensuring the safety of all foods would best be accomplished by a single, consolidated food

safety agency. We asked that the Congress consider forming a blue-ribbon panel to study the feasibility of this and other approaches to strengthening food inspection. Such a panel could provide the means to build consensus on the design of a new food safety system.

CONCLUSIONS AND RECOMMENDATIONS

The present meat and poultry inspection system relies primarily on organoleptic inspections that are not capable of detecting microbial pathogens, which constitute the greatest public health risk. To better protect the public from foodborne illnesses, FSIS must move to a modern, scientific, risk-based inspection system.

To achieve this goal, we recommend that the Secretary of Agriculture direct the FSIS Administrator to (1) develop a detailed strategic and operational plan showing how it intends to achieve a more effective inspection system, (2) work with all interested parties to build a consensus on the design of a new inspection system, and (3) seek needed legislative changes and obtain congressional guidance on the objectives of the meat and poultry inspection system.

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

(Attachment follows:)

GENERAL ACCOUNTING OFFICE AND OTHER REPORTS
ON THE FEDERAL FOOD SAFETY INSPECTION SYSTEM SINCE 1977

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Meat and Poultry Inspection: The Scientific Basis of the Nation's Program

Statement of

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before the
Subcommittee on Department Operations and Nutrition
and
Subcommittee on Livestock
Committee on Agriculture
U.S. House of Representatives

March 16, 1993

Good morning, Mr. Chairman and members of the Committee. I am Michael Doyle, a member of the Food and Nutrition Board, a division of the Institute of Medicine of the National Academy of Sciences and professor of Food Microbiology at the University of Georgia. 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.

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 health 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 identified 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 current 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, CDC, 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.

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON AGRICULTURE
WASHINGTON, D.C. 20515

Department of Operations and Nutrition Subcommittee, and
Livestock Subcommittee, Joint Public Hearing
1300 Longworth House Office Building
Washington, D.C.

Subject:
Review of Meat and Poultry Inspection System
of the Department of Agriculture

Testimony of:

Joseph V. Rodricks, Ph.D.
Senior Vice President
ENVIRON Corporation
Arlington, Virginia

1987 Chairman, Committee on Public Health Risk Assessment
of Poultry Inspection Programs
National Academy of Sciences, Washington, D.C.

March 16, 1993

Mr. Chairman and members of the Subcommittee, I am Dr. Joseph V. Rodricks, a founder and Senior Vice President for Health Risk Analysis at ENVIRON Corporation, Arlington, Virginia. My background includes 15 years as a scientist at the FDA, specializing in the evaluation of health risks associated with foods, and more than 12 years as a consultant to industry and government on assessing human health risks associated with agents in our environment. In 1985 I was asked by the National Research Council to serve as Chairman of the Committee on Public Health Risk Assessment of Poultry Inspection Programs. This committee was assembled at the request of the FSIS, and was asked to develop a risk assessment model to assist the agency in developing poultry inspection procedures that would best protect the public's health. Our committee, which consisted of experts not only in risk assessment but also in all of the various technical disciplines related to problems of biological and chemical contamination, produced its report in 1987. I believe what our committee had to say in 1987 is still relevant today, not only to poultry inspection but in important ways to meat inspection as well. I shall summarize our findings and recommendations.

I shall first say a little about risk assessment and of its importance in solving the type of public health problem that is under discussion here today. We should think of risk assessment as a highly systematic means for organizing information and knowledge concerning public health problems -- whether biological or chemical -- that arise in our environments. Such an assessment is the only sure way for us to understand the magnitude of particular problems, and most importantly, provides the most systematic means available for identifying the principal sources of risk and thereby the types of actions and interventions that will most effectively reduce them. Because it highlights uncertainties in our knowledge, risk assessment is also a highly valuable guide to the types of investigations that are necessary to develop risk management programs that are scientifically based and that the agency could use to develop inspection programs that are more clearly oriented to health protection goals.

In developing a risk model for FSIS we identified five stages where contamination may occur: 1) production; 2) slaughter; 3) processing; 4) distribution and 5) preparation and consumption. Each of these stages requires its own type of risk assessment, and our report contains detailed discussions of how each might be approached. We emphasized that such an assessment, guided by our model, would be a reliable and scientifically sound guide to identifying critical risk management points and for devising the most appropriate remedial measures. Additional investigations need to be undertaken before implementation of more effective public health programs; our risk model, properly applied, would provide a guide to the necessary investigations.

Our committee, like many others, found that contamination with Salmonella or certain other microorganisms is the most significant public health risk posed by consumption of chickens. Current inspection procedures, however, rely heavily on visual and manual examination of each bird as it is readied for retail sale. We found no evidence that such procedures provide effective protection against this type of microbial contamination.

Our committee recommended that FSIS develop the necessary data to allow shifting of emphasis from the current bird-by-bird inspection procedures to a system that involves more rigorous testing of a random sampling of chickens for both microbial and chemical contaminants. We propose that microbial and chemical tests be performed on a statistically significant sample of chickens at each processing plant and that a smaller sample of chickens be frozen and sent to a central laboratory for more detailed studies. Some testing of this kind is performed now, but it is not frequent enough, nor are the results processed quickly enough, to ensure detection of problems before chickens are marketed.

The backbone of the current inspection system is the observational skill of local inspectors. An inspector has between one and three seconds to examine a bird, looking for bruises or obvious signs of poultry disease.

Carcasses that emerge from the processing line may appear clean to the naked eye, and yet still be contaminated with microscopic agents such as Salmonella. These organisms are commonly found in fecal matter and come in contact with the edible flesh of the chicken during the scalding, plucking and evisceration process. To avoid this contamination, greater efforts should be made to prevent gastrointestinal contents from touching the flesh during processing and to avoid cross-contamination between birds. This is technically feasible, but would require modification in poultry processing equipment, especially pluckers and chillers.

Chicken can become contaminated in other ways as well. During the production process they may be fed impure grain or water containing microbial agents or chemical contaminants.

As I have said, in developing the risk assessment model for FSIS, we identified five stages where contamination may occur, and all need attention. We do not know which stage or stages contribute the most to contamination problems, but the risk assessment model we provided can be applied to identify the critical stages for devising remedial measures appropriate to each of the stages.

We recognized that FSIS does not have jurisdiction to regulate poultry products beyond the slaughterhouse. It is, however, the federal agency charged most directly with ensuring that poultry is safe to eat. This is why we urged FSIS to take the lead in coordinating efforts with the Environmental Protection Agency, the Food and Drug Administration, and state and local health departments to detect and prevent contamination at each of the five stages we identified.

What did we think our report meant for consumers? Poultry is a nutritious and desirable part of the American diet. We did not want to discourage anyone from eating chicken.

We did want consumers to be aware of the problem and to handle and cook chicken properly. The rules for doing so are so important that we suggested that labels describing proper cooking and handling be provided on poultry products at the time of sale. We also proposed that FSIS develop education programs for workers in the poultry industry and commercial food establishments.

Our major findings then were these: Contamination of poultry products with pathogenic microorganisms such as Salmonella is now occurring at high levels. While the data are not complete, and while poultry is not the only source of these microorganisms, we believe this contamination, wherever it occurs, plays a major role in the millions of cases of food poisoning occurring each year. The Food Safety and Inspection service, other relevant government authorities and the poultry industry should work to minimize this contamination by: 1) random sampling of chickens during processing for both microorganisms and chemical contaminants, using contemporary, statistically based quality control procedures applied in other areas of food safety assurance; 2) monitoring of feed, water, and other environmental influences during production; and 3) conducting studies at all stages to determine the major sources of contamination and to learn how to control them. We also suggested that labels be provided on poultry products to inform consumers about proper cooking and handling. The risk assessment model we developed provides a systematic framework for undertaking these activities and should be applied by FSIS to guide its risk management programs. Until this is done it is difficult to see how more effective public health protection could be achieved.

STATEMENT OF
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BEFORE
THE HOUSE AGRICULTURE SUBCOMMITTEE ON DEPARTMENT OPERATIONS
AND NUTRITION AND THE SUBCOMMITTEE ON LIVESTOCK

March 16, 1993

Mr. Chairman and Members of the Subcommittee, I am pleased to have this opportunity to appear before you today. I am Bob Cassens, Professor of Meat Science and Muscle Biology at the University of Wisconsin. I have been employed there since 1963 as a teacher and researcher in the areas of control of muscle quality, application of preservation techniques to meat, and assessment of safety of cured meat.

I have submitted a written statement and request it be inserted into the record.

I am representing CAST (Council For Agricultural Science and Technology) and IFT (Institute of Food Technologists). The former is a coalition of 31 scientific societies devoted to advancing the understanding and use of food and agricultural science and technology in the public interest. The latter is a professional society of 26,000 members dedicated to satisfying human needs for nutritious and safe food.

You have asked for my opinion about the existing federal meat and poultry inspection system and how it can be improved.

I believe the present system works well for what it was designed to do more than 80 years ago--that is to prevent entry of diseased and damaged meat into the human consumption chain and to ensure that the operations converting food animals to meat are conducted in a sanitary and appropriate manner. This task is accomplished by on-site, direct, visual inspection.

I also believe the system must be modernized and improved.

There are three means for doing so, which are: (1) adoption of scientific technologies that are proven to be effective and safe, but are not yet used, (2) utilization of scientifically trained people, and (3) investment in developing more and better scientific technologies for the future.

The simple message I wish to leave with you is that more science, in the form of usable technologies, trained people, and commitment for the future must be incorporated into the present system.

Three examples illustrate my first point that there are indeed, existing, proven technologies that should be used but are not presently being employed in the inspection system. They are: (1) irradiation, (2) so-called carcasses rinses, and (3) HACCP (hazard analysis critical control points).

Irradiation of meat raw materials and raw meat products could be used to ensure microbiological safety of meat and poultry just as pasteurization is used to make milk safe. The technology has been throughly researched. In fact, when I began Graduate School at the University of Wisconsin in 1959, there was research underway, in cooperation with the United States Army Quartermaster Corps, on organoleptic, physical, and chemical characteristics of irradiated pork. More than 30 years of research has clearly established that irradiation of foods is an effective and safe process.

Another proven means to control the surface microbiological contamination of carcasses is to spray or rinse with organic acids, trisodium phosphate, or chlorine. Abundant scientific evidence exists to show these methods are both effective and safe.

Many would view the slaughter site as the primary sanitary concern. However, slaughter is only one part of the total system that delivers meat and poultry to the table. It starts with animal production on the farm and includes transportation and delivery of the animal to the slaughter plant. Following slaughter there is distribution, retailing, and finally handling and preparation by the consumer.

HACCP is a system developed to ensure that the food taken aloft by astronauts is safe. The system works and is especially effective in a complex multistep and multisite production scheme as described above.

Effective use of HACCP concentrates on only the few critical points in a process. Temperature is a good example in the meat industry. Processed meat, contrasted to raw meat, may undergo a heat treatment that virtually eliminates pathogens. Perhaps, a system similar to pasteurization of milk or canning of low-acid foods should be developed where the industry is responsible but an independent organization certifies control.

If the above methods are so effective why aren't they being used? Limited regulatory approval in certain cases permits irradiation and carcass rinses, and some companies employ HACCP successfully on their own initiative. However, the consuming public is confused about food safety issues and has developed an anti-technology attitude. Adoption of effective technologies is therefore inhibited. This situation was generated and continues

to be driven by certain professional activists and the media. Deliberate effort has been made to scuttle new technologies such as irradiation. The ultimate result has been that industry is unwilling to take the risk of introducing a new technology.

There is no doubt that modernization of meat and poultry inspection must occur. The changes must be science-based. Therefore, scientifically trained people must be employed not only to guide and manage the program but also to work in the plants on a day-to-day basis. People must be trained in microbiology, risk assessment, new preservation techniques, statistical evaluations, quality management and new products, to list but a few areas. As more testing is incorporated into the system, the employees must have the ability to evaluate and interpret results. Genuine educational programs also must be directed at food handlers and consumers.

Finally, in a science-based inspection system, provision must be made for improving technologies, devising new science, and then applying them in the system. Science must be directed at improvement, and the inspection system must be sufficiently flexible to incorporate new scientific information when it is demonstrated to be effective and safe.

Two examples to illustrate needed scientific advancements by scientific research follow.

There is a powerful need for rapid detection methods--especially microbiological. Problems cannot be dealt with when a wait of several days is required for test results. IFT released their critical research priorities on March 9, 1993 and one was "to develop better testing methods for microbiological contaminants and disease agents." The benefit will be to reduce the spread of foodborne diseases and minimize the occurrence of pathogens.

Methods are needed to trace-back animals so that sources and pools of potential health hazards can be eliminated. Levels and kinds of microorganisms must be tracked so that trends and changes can be spotted and eventually predicted, controlled, and eliminated.

Complex food safety issues have been identified in recent years. Scientific knowledge and technologies will have to be used to solve the problems. Some technologies are available and must be adopted while others must yet be developed.

There are no absolutes in science, and there are no one hundred percents in food safety. Perfect should be the goal, however, and the full power of science must be used to attain the goal.

Statement Presented to the Joint Hearing of the House Agriculture Subcommittee on Department Operations and Nutrition and the Subcommittee on Livestock Regarding the Federal Meat and Poultry Inspection System

March 16, 1993

Presented by

James H. Denton
Professor, Department Head and Director of the
Center of Excellence for Poultry Science
University of Arkansas

on behalf of

The Council for Agricultural Science and Technology
Ames, Iowa

Mr. Chairman and members of the subcommittees, I am pleased to have the opportunity to appear before you today. I am Dr. J. H. Denton, Head of the Department and Director for the Center of Excellence for Poultry Science at the University of Arkansas.

The current Meat and Poultry Inspection (MPI) system has been indicted as being flawed, out dated and not science based. Because of the failure to modernize, MPI is viewed as one of the primary causes for the tragedies associated with the recent foodborne illness outbreak involving improperly cooked ground beef patties. This is unfortunate, at best, for an agency which has been the primary focus of meat and poultry safety certification for many years. Indicating that the inspection system currently in use has no basis in science ignores many of the positive advances resulting from the combined efforts of the meat and poultry industries and the FSIS MPI system. In order to better understand the nature of the current system, and make informed decisions regarding the methods to be employed for improving the system, we must briefly review, without great detail due to time constraints, the evolution and progress which has been made under the current MPI system.

The MPI system was established during a time in which little was known regarding the microbiological aspects of food safety. The primary focus was to eliminate animals which were obviously diseased, physically damaged or contaminated with foreign material as being unwholesome for human consumption. With the increase in scientific knowledge occurring over time the meat and poultry industries and the MPI system became more aware of the need for microbiological control as part of an efficient processing system. Many of the current slaughter and processing techniques are the direct result of scientifically based information; such as 1) the use of stainless steel equipment which is easily cleaned and sanitized, 2) carcass sprays, washes and rinses designed to minimize microbial numbers and the effective use of temperature to further reduce or prevent microbial growth. The list of these types of techniques and systems is extensive, all with one goal in mind, providing American consumers with the highest quality and safest meat products possible.

The questions which we must address today, and in the future, are really quite simple. Number 1 - Are we doing the very best job of providing safe high quality meat and poultry products that is possible? If we are honest with ourselves, the answer we would give is Yes, we are giving it our best effort, but No we have not achieved the best we desire in meeting this challenge. We cannot afford to become self assured and complacent. We must always seek ways to improve the current system because it is not based on perfection, only our best effort toward the perfect system.

Question number 2 - In order to improve the current mission of assuring meat and poultry product safety, should we abandon the current system? The answer for this question, if we are honest with ourselves, is No, not right now, but Yes as we continue to enhance the scientific basis of the system. By using this approach we are not abandoning an effective system, rather we are continually striving to improve the system thereby forcing it to change as our knowledge changes. We cannot allow the system to become so inflexible that improvements brought about by good science cannot be implemented. For example, adoption of HACCP as a management tool appears to be causing a radical shift in the current system. In reality, because the HACCP model is based in sound science it really is a redirection of existing resources for use in a more efficient system. **However, these changes will be dependent on sound science based information and effective training for FSIS MPI personnel to ensure correct application of the system. More of the responsibility is placed on industry, since HACCP is an industry driven management tool, with oversight and monitoring the responsibility of MPI and less emphasis on visual inspection.**

The key point here is the fact that MPI, like the scientific basis for making food safety decisions, is a process. The MPI system which exists in 1993 is not the same system it was in 1983 or for that matter in 1973. The inspection system is only as

effective as the science which supports it. Many discussions have debated the merits of science based decisions versus value based decisions as though they are separate processes. **The fact is that the information derived from science serves as the guide for the value based decision making process.** Accurate information is the only acceptable basis for making decisions, otherwise we make uninformed decisions based on fear, superstition or misinformation.

As I view the current situation, MPI is at a crossroad, presented by the current chain of events, which is destined to force change in the system. However, this change must occur logically, systematically and cannot be change just for the sake of response to a crisis event. Inspection is a part of the marketing process for meat and poultry, as science is a process for expanding our knowledge base. In order to really improve the system we must base any changes on the very best science available.

The origin of our safety related sound scientific information has generally been from three identifiable sources; 1) the research from the meat and poultry industries, 2) research from universities and government laboratories and 3) data from the MPI regulatory agency. Additional information obtained from the Centers for Disease Control also assists in understanding the factors which influence and, in some cases, cause foodborne illness outbreaks. The scientific information obtained through the combined efforts of these groups has resulted in greater understanding of time/temperature relationships, sources of contamination, means of control and reduction for both pathogenic bacteria related to human health and spoilage bacteria resulting in unnecessary product losses as well as the mishandling factors which result in outbreaks of food borne illness. The key point in obtaining good scientific data is to remember that it must come from refereed scientific journals. There is no intent to unnecessarily criticize the news media, however, for the purposes of the food safety decision making process it is important to understand that they are not refereed scientific publications and generally contribute very little to the scientific solutions of technologically complex problems. Rather than providing factual information which may actually contribute to the solution of these problems, the sensational and emotional nature of these situations often hinder the effective use of our somewhat limited resources in meeting these challenges. Emotion must be removed from the process as much as possible.

Specific Recommendations for Improving the MPI System

The current situation of highly focused attention to food safety concerns provides a tremendous opportunity to make significant strides in devoting an even greater emphasis to science based inspection systems. Even though the current inspection system has served very long and very well, MPI should not look back to the previous system based on extensive inspection for assuring food safety, but

rather, should look to the future with increased emphasis on food science based systems. Safety and quality must be built in to the meat and poultry products because they can not be inspected in to the product.

The most effective Management tool available for achieving the goal of a safe and quality meat and poultry supply is the HACCP (Hazard Analysis Critical Control Point) program model. **The HACCP program for safety, which is a subset of Total Quality Management, is not an inspection program.** It is the model by which the control points (CP) for microbiological reduction for raw meat and poultry products are identified for the purpose of exercising a greater degree of attention and thus limit or reduce (control) the potential for bacterial increases to occur; and the critical control points (CCP) for cooked products are identified for the purpose of preventing the survival or the re-introduction of microbial contaminants to cooked products which may be consumed without additional heating. When the HACCP model is used for raw products, the system emphasis is primarily on CP, whereas the model applied to cooked products relies on CCP, the first of which is cooking. Additional CCP are the points at which there is opportunity for re-introduction of microbial contaminants to foods which are ready to consume as purchased. The factor that makes them Critical CP is that no additional heat is applied.

The greatest danger associated with improperly applying the HACCP model to raw meat and poultry products as an inspection system is unrealistically raising the expectations of consumers for the belief that they are receiving a raw product that is free of pathogens. This expectation, a raw product which is essentially sterile, can not be achieved by any technology currently approved for use. This is further complicated by the fact that animals are not produced in sterile environments. The scientists and technologists in the agriculture and food industries cannot selectively eliminate any specified pathogenic or microbial population because they do not control all of the known points of entry for contamination to potentially occur. The entire human population does not exist in a sterile environment. Points of opportunity for re-contamination of foods exist at multiple locations along the food marketing chain. The most significant opportunities for these incidents to occur are after the product leaves the processing plant. This in no way diminishes the responsibility of the processor for maintaining the safety of the meat and poultry supply at the highest level possible. It is because the greatest opportunity for errors in mishandling to occur are after the product leaves the plant that maintaining the highest safety margin at this point is absolutely imperative to the success of the remainder of the marketing chain.

The greatest contributions which the MPI system can make in assuring he continued improvement of meat and poultry safety is to 1) place the highest priority on the most rapid adoption of sound, food science based inspection systems and 2) continue to serve as a resource for information which can be included in a sound, science based education program for all levels of the food marketing system.

The recommendations of the 1992 National Food Safety Workshop which was sponsored by the Cooperative Extension Service from the states of Arkansas, California, Indiana, Maryland, Texas and Virginia cannot be over emphasized. **The most effective solution to the majority of food safety issues is education.** The education program, regardless of whether targeted to producers, processors, regulatory personnel, distributors, food service, food retailers or consumers, must be developed using sound, science based information from credible sources. This information should be shared with health and medical professionals, news media and legislative officials in order to provide consistent, non-conflicting messages with the understanding that honest differences of opinion may occur.

The National Educational Forum on Food Safety Issues (NEFFSI), formed as part of the specific recommendations which were outlined during the 1992 Food Safety Workshop, was developed with the mission of encouraging science based discussion of food safety issues. The initial project of NEFFSI is to co-sponsor, in cooperation with the American Medical Association (AMA), a conference targeted to practicing physicians entitled "Food Safety and Foodborne Illness: An Opportunity for the Practice of Preventive Medicine" in November, 1993. This effort, being planned by committed professionals from the medical community and the Cooperative Extension Service of the Land Grant University System, further validates the position that education involving all of the affected groups is the only real solution to our food safety concerns. The Cooperative Extension Service is also the most credible source and most effective delivery system for communicating food safety education programs to the widest range of target audiences.

In summary, I would encourage the committee to:

- Support the adoption of HACCP as an industry driven management tool through broad based education targeted to all levels of the food chain from production to table;
- Support the shift of MPI, on the basis of sound science, to a food science based inspection system which relies on information generated by a system such as HACCP, with oversight and monitoring the responsibility of MPI;
- Support the process of education as the most effective means to address food safety issues;
- Recognize the Cooperative Extension Service as the most credible source and most effective delivery system of sound, science based educational programming for food safety issues because of the relationship with the Land Grant University System.

Thank you for allowing me to participate in your hearing and the discussions regarding food safety and the Meat and Poultry Inspection system.

American Public Health Association
Statement for Meat Inspection and Food Safety Hearing
House Agriculture Subcommittee on Department Operations and Nutrition
March 16, 1993

The American Public Health Association (APHA) believes that now is the time to reexamine the monitoring and inspection services of meat and poultry production and processing facilities currently under the Food Safety and Inspection Service of the Department of Agriculture. The recent episode linked to Jack in the Box restaurants in the Northwest is not the first time in recent years that we have seen widespread food-borne bacterial poisoning in the U.S. It is imperative that the health of our nation's citizens should be protected from these avoidable perils.

APHA believes that this public health incident could have been prevented. We find it totally unacceptable that, according to a recent study, the E. coli bacteria contaminates over 3% of the raw ground beef sold at supermarket counters. This ongoing health hazard is unacceptable and is symptomatic of the deterioration of our food safety system.

Our Association believes that the methodology of inspections should entail much more than simple random visual examination of meat or food products. Modern microbiological testing, updated quality assurance in meat inspection, food services inspections, food handler training, and disease surveillance should all be included.

Furthermore, assurance of the food supply's healthfulness should be the fundamental responsibility of the federal, state and local agencies that oversee the food supply. The agency designated to perform health inspections should have a clear public health mission.

We have asked President Clinton to convene a panel of experts to determine what changes are necessary in the food inspection system and which federal agency is best suited to carry out that program. The public health community stands ready to assist this Administration in rectifying the current inspection problems and enriching the health of the nation's citizens.

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