S. HRG. 103-1065

THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (S. 958, S. 1478, AND S. 2050)

HEARING

BEFORE THE

SUBCOMMITTEE ON
AGRICULTURAL RESEARCH, CONSERVATION,
FORESTRY, AND GENERAL LEGISLATION
OF THE

COMMITTEE ON AGRICULTURE,
NUTRITION, AND FORESTRY
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

ON

THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

JULY 28, 1994

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry

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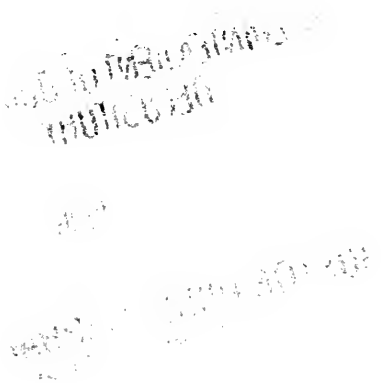

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APPENDIX

THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (S. 958, S. 1478, AND S. 2050)

THURSDAY, JULY 28, 1994

U.S. SENATE,
SUBCOMMITTEE ON AGRICULTURAL RESEARCH, CONSERVATION, FORESTRY AND GENERAL LEGISLATION, OF THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:30 p.m., in room SR–332, Russell Senate Office Building, Hon. Thomas A. Daschle, Chairman of the subcommittee, presiding.

Present or submitting a statement: Senators Daschle, Pryor, Lugar, Cochran, and Craig.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. The hearing will come to order.

Today we meet to gather information for our deliberations on the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act and also certain provisions of the Federal Food, Drug and Cosmetic Act.

FIFRA is always a topic of great public concern, and that is as it should be. Nothing is more fundamental to the quality and quantity of human life than an assured supply of wholesome, appetizing food. The one near certainty in life is that food will be both a fundamental need and a fundamental pleasure for most people.

In America, we are generally fortunate. We do not suffer through the periodic famines that afflict too much of humanity. That blessing is a tribute both to our natural environment and the unnatural productivity that allows a tiny fraction of our population to feed not only our Nation, but to help feed people in other Nations as well.

Indeed, the fruits of the Earth remain the single largest category in our favor in international trade. Sometimes we tend to forget that fact.

It is our technology as well as our hardworking farmers who apply that technology that make all of this possible. However, technology has the capacity to create ill as well as good if we do not maintain our vigilance.

That is why FIFRA and FFDCA were created, and why they remain essential.

Our technology evolves swiftly, sometimes too swiftly for legislators and even producers to keep pace. Now we need to reexamine our agricultural technology with the purpose of keeping

our farmers the world's most productive and keeping our agricultural technology the world's best.

The first imperative is safeguarding human health through assuring the safety of American food supply.

A great concern in this regard is whether present standards adequately protect infants and children. Children are not just little adults. They are unique in diet and physiology.

This fact was not taken into account in existing law, some provisions which date back to the 1940's and 1950's. Now we know better. The question for us as legislators is what constitutes an adequate standard for food safety for children.

Is it the same standard as applies to adults, or is it a more conservative benchmark? Does a sufficient safety margin exist, or must the margins be withdrawn? That is a fundamental consideration that we must address today that we did not have to address in the past. On the other hand, there are other considerations—dozens of them. For with knowledge comes responsibility.

Notably, today's considerations include environmental, enforcement, and economic concerns. Considering the environment we must ask whether legislation is adequate to encourage and expedite replacing more dangerous pesticides with more benign modern compounds and with earth-friendly farming practices.

We must ask: "How do we encourage rather than impede the shift to improved or alternative technologies that both produce foods we need and better protect the entire ecosystems that include the cultivated lands that sustain our Nation?" We must decide whether we are being over- or under-zealous in setting residue requirements for food.

Considering the requirements of producers we must decide how to speed the registration of much needed minor-use pesticides to give them the tools they need to produce the foods Americans demand.

The situation regarding the unavailability of minor-use pesticides is a major problem for those who work on the land.

We must decide whether the rules we enact will make us partners or parole officers to America's farmers. Also, I am certain that my fellow legislators prefer partnership.

This philosophy also holds true for the industries that support our agricultural producers and deliver our food products to consumers. We must make decisions on sound scientific bases and in ways that minimize economic dislocation. We face many decisions. We must decide what constitutes "negligible risks" in pesticide residues, and whether to mandate "zero risk" in some instances.

We must deliberate about the Delaney clause with its mandate of zero risk in regard to some carcinogenic compounds. Should we choose between multiple risk measurements and standards which ensure food safety, or simpler standards that measure pesticide residues at a single point in the chain of food production and preparation.

These are tough issues. We are fortunate to have a panel of distinguished witnesses to guide and help us in our deliberations. I thank each of them for their time and effort, for their prep-

aration and their travel, for the sacrifices that they made to be with us today.

Testifying are Carolyn Brickey, the executive director of the National Campaign for Pesticide Policy Reform; Jay Vroom, the president of the National Agricultural Chemicals Association; Dr. Philip Landrigan, the chairman of the National Academy of Sciences Committee on pesticides in the Diets of Infants and Children; Dr. Stephen Ziller, vice president of Scientific and Technical Affairs for the Grocery Manufacturers of America; Albert Meyerhoff, a senior attorney for the National—or excuse me—the Natural Resources Defense Council; Juanita Duggan, the senior vice president for Government Affairs of the National Food Processors Association; Jim Bender a farmer from Weeping Water, Nebraska and author of the book "*Future Harvest*"; and Keith Eckel, a farmer from Clarks Summit, PA and the president of the Pennsylvania Farm Bureau Federation.

Let me invite all of them to our table this afternoon and as they are coming to the table let me call upon my Colleague and friend from Idaho, the Ranking Member in this subcommittee, Larry Craig.

STATEMENT OF HON. LARRY E. CRAIG, A U.S. SENATOR FROM IDAHO

Senator CRAIG. Mr. Chairman, thank you very much. Please do come up and take your seats so that the Chairman can move us expeditiously. I want to thank you and the Chairman of the Full Committee for bringing this panel together and holding this hearing.

Mr. Chairman, while I think all of us recognize the importance of this hearing I hope that we continue to focus on the goal at hand. Also, that goal is, I think one that all of us share; to ensure an adequate wholesome and economical food supply for our country that we can without reservation not only provide the American consumer, but continue to share with all the world.

Now, when I say that, Mr. Chairman, I think it is very important that I quote two gentlemen who I have some respect for in the work they have in areas of safe food, and understanding of pesticides and the issue of chemicals. The Farm Bureau folks quoted Dr. C. Everett Koop in the hearings in the House and this was the quote. I thought it was significant. Dr. Koop said: "I do not know of a single instance where exposure to pesticides on foods in the marketplace is a source of any danger to children or adults." He says: "It's a risk of zero."

Dr. Bruce Ames, the University of California at Berkeley says: "The attempt to prevent cancer by regulating low levels of synthetic chemicals by using worst-case, one-in-a-million risk scenarios is not scientifically justified. It diverts resources from much more important risks. Perversely it decreases consumption of food that might even prevent cancer."

Therefore, I think there are several issues that must be addressed as we look toward resolving our concerns. The legislation before us that these ladies and gentlemen will speak to today along with their own knowledge attempts to address that in a variety of

ways. I'm a supporter of S. 1478 that Senator Lugar, who has just arrived along with Senator Pryor, have introduced.

Clearly I think, Mr. Chairman, the Delaney clause and FIFRA section 408 and the contradictions amongst those two items have got to be resolved. Single regulatory standards for fresh and processed products is an issue that has to be resolved. Length of time to remove unsafe pesticides as well as approval for newer, safer products as technology has developed is an issue of importance.

The loss of minor-use pesticides must be resolved.

I come from a State that has a variety of counties that really provide unique products to the country in the sense of great supplies of seeds and a variety of food products. Minor-use pesticides are very important to the well being of those economies by providing for them and the variable risk benefits considerations that I think have to be developed. There is a lot to be talked about.

I thank you for calling the hearing. Those are some of my concerns and I would ask unanimous consent that my full statement become a part of the record.

Senator DASCHLE. Without objection. Thank you Senator Craig.

[The prepared statement of Senator Craig follows:]

STATEMENT OF SENATOR LARRY E. CRAIG

Mr. Chairman, I would like to thank you for calling this additional hearing. This is a very important subject and there are many outstanding issues facing American agriculture and the general public as it relates to the safe and effective use of chemicals.

I believe, Mr. Chairman, that as we examine this issue we must keep our focus on the goal. That goal, I believe all share, to ensure that we maintain an adequate, wholesome and economical food supply that we can, without reservation, not only provide for the American consumer, but continue to share with the world.

Statements by two recognized professionals, as quoted by Mark Maslyn of the American Farm Bureau in the House Agriculture Hearing on June 15, could be instructive to this committee as well:

Dr. C. Everett Koop:

"I do not know of a single instance where exposure to pesticides on foods in the marketplace is a source of any danger to children or adults. It's a risk of zero."

And Dr. Bruce Ames of the University of California at Berkeley:

"The attempt to prevent cancer by regulating low levels of synthetic chemicals by using worst-case, one-in-one million risk scenarios is not scientifically justified. It diverts resources from much more important risks. Perversely, it decreases consumption of foods that help to prevent cancer."

There are several issues that must be addressed as we look to resolving this issue:

1. The Delaney clause and FIFRA section 408 contradiction must be resolved.
2. Single regulator standards for fresh and process products.
3. Length of time to remove unsafe pesticides as well as approval of newer, safer products as technologies are developed.
4. The loss of "minor-use" pesticides must be resolved.
5. A viable risk-benefit consideration must be developed.

I have joined with Senators Pryor and Lugar in cosponsoring S. 1478, in an attempted to address these issues.

On the other hand, it appears to me that the administration's approach to resolving these issues seems to be shifting the burden from the Federal bureaucrats onto the backs of the individuals it regulates. For example, as I read the administration proposal, if registration is not renewed by the end of a 15-year deadline, a 1-year extension could be granted. At the end of that year, the registration would disappear. The effect would be that if EPA fails to act, or if its own roadblocks prevent

the registrant from meeting the deadline, farmers lose the use of safe chemical products and consumers suffer as well. This is a major shift in responsibility.

The administration's pesticide policy proposal would extend current Farm bill pesticide recordkeeping requirements on restricted use chemicals to all chemicals, *for farmers only*. At the same time, the proposal would amend the Federal Food, Drug and Cosmetic Act. The EPA would be required to assess and identify nondietary exposure in the home, water, lawn, work place, and elsewhere, and include these exposures in setting food use tolerances. Agriculture's ability to use a chemical on a farm, where it can be controlled and measured, would ultimately be limited by other uses which cannot be controlled or measured on a national basis.

These are important issues before the committee. I look forward to the testimony of the witnesses and working with the Chairman and other Members of this committee to resolve the outstanding issues.

Thank you, Mr. Chairman.

Senator DASCHLE. Our Ranking Member of the Full Committee is here, Senator Lugar, and I would invite him for any opening remarks that he would like to make.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Senator LUGAR. Thank you very much, Mr. Chairman. I am pleased to join you and my Colleague, the Senator from Idaho, and I congratulate you as he does in holding the hearing and taking testimony on the administration's food safety legislation introduced by the Chairman of our committee, Senator Leahy and Senator Kennedy, as well as your consideration of the food safety legislation which Senator Pryor and I have introduced.

The Senate Agriculture Committee recently heard testimony from administration witnesses with regard to food safety legislation. At that hearing, I expressed some concerns with several provisions of the administration's proposal and contrasted that approach with the Pryor/Lugar legislation. I will not go into the same detail today, but would note a few differences that are major, I believe, for the record.

In reforming the Delaney clause we need a science-based, negligible-risk standard such as that found in S. 1478 which would give the EPA flexibility to take into account advances in science when making tolerance decisions. Our bill also allows for the consideration of benefits in setting tolerances and recognizes the role of pesticides in ensuring an adequate, wholesome, and economical food supply.

Finally, S. 1478 does address the issues raised in last year's National Academy of Sciences Report about pesticides in the diets of infants and children. The bill directs EPA, FDA, and USDA to implement the recommendations of the report recognizing the need for obtaining better information on what children eat and what is in the food they consume.

While we can always work for improvements, it is important to note that our food supply in this country is safe, that our Nation's consumers have access to a varied and abundant array of food.

Again, I appreciate the subcommittee holding the hearing and I look forward to being a part of this hearing today. Thank you, Mr. Chairman.

Senator DASCHLE. Thank you, Sir.

Senator CRAIG. Mr. Chairman, could I ask unanimous consent also that a statement by Senator Cochran become part of the record?

Senator DASCHLE. By all means.

[The prepared statement of Senator Cochran follows:]

STATEMENT OF SENATOR THAD COCHRAN

Thank you, Mr. Chairman for holding this hearing to address a very important issue. This committee is interested in a commitment to insure that the citizens of the United States have access to safe and wholesome food. We must base our actions and our decisions on the facts and reliable research.

I hope that we will be able to use resources, private and public to provide sound scientific information concerning the food and agricultural policy impacts of the various pesticide reform proposals.

Consumer fears about the health risks of food have often been influenced by sensational reports, which have not always been based upon sound science.

As this committee begins to address pesticide and food safety reform legislation, we must not lose sight of its impact on farm income and productivity, while insuring that our consumers have the safest and most abundant choices of food products.

I look forward to working with the committee, the administration, and with the various sectors of the food and agricultural community in addressing legislation to make the safest food supply in the world even safer. I have no doubt that this can be accomplished without adversely impacting U.S. agricultural production if we are all committed to working together and base our decisions on sound science.

Thank you again, Mr. Chairman for holding this hearing. I look forward to the testimony presented here today.

Senator DASCHLE. We will now proceed with our panel. Let me begin by welcoming back to this committee someone who is no stranger, Carolyn Brickey.

STATEMENT OF CAROLYN BRICKEY, EXECUTIVE DIRECTOR, NATIONAL CAMPAIGN FOR PESTICIDE POLICY REFORM, WASHINGTON, DC.

Ms. BRICKEY. Thank you, Mr. Chairman. It is a pleasure to appear before what has to be the most distinguished committee in this Congress, and I say that without any bias whatsoever.

Thank you for an opportunity to present the views of the National Campaign for Pesticide Policy Reform about the administration's proposal and other proposals. I am the executive director of the campaign which is a clearing house for a coalition of 51 local and national groups including consumer advocacy, environmental, health, women's civil rights, and pesticide reform organizations.

I am submitting written remarks on the specifics of the legislation, but I would like to talk more generally about the problems posed by pesticides and what we need to do to fix the problems.

First of all, why are pesticides a problem and why do we need to worry about this? Pesticides by definition are fairly dangerous substances because they are designed to kill living things such as insects or weeds. As one farmer told me years ago: *"If it don't kill bugs, Missy, it don't work."*

This is Pesticides 101 as far as I am concerned. Sometimes when pesticides do work they can be potent carcinogens. Research has shown us that others can cause birth defects, damage to central nervous system, the immune system or reproductive organs. Some pesticides have been linked in research to breast cancer in humans while others interfere with hormonal function and may be associ-

ated with the substantial increases in cancer of the reproductive organs that have occurred over the last 30 years.

Some studies of children born in areas with high pesticide use suggest higher rates of limb abnormalities in newborns. Other studies indicate that pesticide use in homes and gardens is related to a seven-fold increase in the risk of childhood leukemia.

Just as canaries were used to signal that the air in the coal mines was dangerous to miners, the disturbing events in the reproductive health of wildlife including eagles, alligators, and fish may be a signal that some pesticides pose a serious threat to human health over a long period of time.

Meanwhile, EPA regulates exposure to pesticides as though people were exposed to one pesticide at a time. In fact, we are all exposed to mixtures of pesticides in our food each day and in our environment. The health effects of all these pesticides is not known.

As parents you and I make a point of feeding our children fruits and vegetables as part of a balanced healthy diet and we should.

Yet, according to the National Academy of Sciences, children are at a greater risk for exposure to pesticides, not only because they eat a lot more fruits and vegetables than adults per unit of body weight, but also because of their biological sensitivity. All of their major organ systems are still developing, and a child's developing body is often highly susceptible to damage by the chemicals in pesticides.

Several different pesticides can be found in a single serving of many foods commonly eaten by children such as apples, bananas, strawberries, peaches, pears, or potatoes. In many parts of the country, particularly in the midwest, drinking water supplies are also contaminated with certain pesticides.

According to data collected by USDA and analyzed by the Environmental Group, in certain instances, up to eight different waxing pesticides have been found on certain fruits and vegetables even after washing, peeling, and coring the fruits and vegetables. This means you cannot always wash the stuff off. Unfortunately, the Government does not currently regulate pesticides on the basis of health considerations alone, nor does the Government regulate pesticides to specifically protect children.

So, what is the solution? There are five things that need to be done if we are going to implement comprehensive, effective pesticide reform and wean ourselves from our chemical dependency. First, there should be a health based standard for raw and processed food. Only a true lack of alternatives to pesticides or an averted health risk should ever be considered when EPA says that a pesticide is actually unsafe; that is, that it exceeds the health standard.

Mr. Chairman, we are not talking about whether pesticides have inherent benefits when they are approved for use. We are, instead, talking about whether more narrow economic consideration should prevail over health risks.

Second, pesticides must be regulated based on the cumulative risk they pose. The risks associated with different pesticides that cause the same health effects can be added together in some instances. For example, if a strawberry has eight different pesticides on it and four of them have neurotoxic effects, perhaps those effects

should be added together as a cumulative effect rather than being looked at individually.

In addition, we need to consider multiple exposures to pesticides not just from food. We drink them in water and our children crawl around them on our carpets when we exterminate our homes. Clearly we are exposed to more than minuscule amounts of pesticides in our daily lives.

Third, we need to make EPA's job easier—not because the Agency is incompetent—it is not—but because there are insufficient resources to overcome a series of regulatory obstacles that the Agency faces in enforcing the law. The impediments that EPA staff face in the current law drain the resources and prevent them from getting their work done. The program is a paperwork treadmill, and the objective becomes managing the paper and not the risk.

Fourth, we need to reduce the overall use of pesticides. Some farmers have already begun to do this as you will hear from Mr. Bender today. The best way to make this happen is to have successful farmers teach other farmers in their own areas how to reduce their use of pesticides.

Some research that we are doing at the National Campaign indicates that the American public is very much behind this idea, Mr. Chairman. They see the train moving forward, they want to see progress in this area, and they want to see the levels of pesticides that people use reduced.

I believe it is important if we are going to talk about substantial progress in sustainable agriculture to attack the chemical inputs directly and try to reduce them. Or else the green payment programs that this committee may explore in the Farm bill will not do anything meaningful to improve the environment.

Thank you very much.

Senator DASCHLE. Thank you very much, Carolyn.

As you were presenting your testimony our Colleague from Arkansas and dear friend, David Pryor, has arrived and I would invite him to make any remarks.

Senator PRYOR. Tom, let me wait until the witnesses have spoken, and I will be glad to chime in after that.

Senator DASCHLE. OK. Very good.

Senator PRYOR. Thank you for calling these hearings, Sir. Thank you.

[The prepared statement of Senator Pryor follows:]

STATEMENT OF SENATOR DAVID PRYOR

I want to commend Senator Daschle for calling today's hearing on proposed pesticide reform legislation. He and his staff have shown tremendous leadership on this and many other critical issues facing this country and especially this country's agriculture sector.

Today, we are once again looking at just one of those critical issues. Farmers all across this country are standing by, helplessly watching, as one after another safe and effective tool to defend their crops is taken away. This circumstance is not occurring because these tools pose a significant risk, but because of a now well-known provision of law known as the Delaney clause.

As I said at the last hearing, I hope we will all work together on this and not turn it into a white hat/black hat issue. Afterall, there are so many places where I believe most of us can agree. For example, we all agree that FIFRA must be reformed to give EPA the ability to quickly remove those chemicals from the marketplace that are found to be unacceptable.

Last September, I, along with Senator Lugar and several other Members of the Agriculture Committee, introduced the Food Quality Protection Act of 1993, S. 1478.

As recommended by the National Academy of Sciences (NAS) report, *The Delaney Paradox,* our bill would repeal the Delaney clause and establish a single negligible risk standard applicable to both raw and processed foods. The Pryor-Lugar bill also retains the consideration of risk assessment in the important decisions of consumer and health benefits—which are only made possible by an adequate, wholesome, and economical food supply. Our bill contains a directive to EPA to implement the recommendations of the NAS study, *Pesticides in the Diets of Infants and Children.* As I understand it, this is the only food safety bill that requires the EPA to implement the complete list of NAS recommendations. In addition, the bill would establish national uniformity of pesticide tolerances in order to preserve our national market for food products moving in interstate commerce. Perhaps most importantly, the bill significantly streamlines the cancellation and suspension procedures in FIFRA so that truly harmful chemicals can be removed quickly from the marketplace, while maintaining appropriate scientific review and opportunities for public participation in cancellation proceedings.

I introduced this bill in order to address the essential features of the law needed to resolve the Delaney clause issues. The scope of the bill is by design limited to eight or nine major elements. My purpose is to bring balance to the debate as we attempt to weigh, on the one hand, the need to have available, safe, effective crop protection tools that have helped create and sustain the safest food supply and the most productive agricultural economy in the world, and on the other hand, the need to protect the public health—Particularly children.

Mr. Chairman, thanks again for calling this hearing. I look forward to hearing from our distinguished panel of witnesses, as well as continuing to work with all interested parties on this vital issue.

Senator DASCHLE. And Now, our second witness, as I indicated earlier, is the senior attorney of the Natural Resources Defense Council—Albert Meyerhoff.

Mr. Meyerhoff, thank you for being here.

STATEMENT OF ALBERT H. MEYERHOFF, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, SAN FRANCISCO, CA

Mr. MEYERHOFF. Thanks very much, Senator. I will try to keep these remarks brief so we will have some time. However, I would ask that the written testimony be part of the record.

Senator DASCHLE. Without objection, the entire statement will be made a part of the record.

Mr. MEYERHOFF. I have been working on issues involving pesticides for about 20 years. The other night, I was reading the floor debates from 1954 to 1958, when the Pesticide Residue Amendment and the Delaney clause was enacted. I must have just not had a good book or something, but I was reading through them and what I found rather intriguing was that many of the same issues that we are debating here today, the same questions were at issue then: How safe is safe? Do we need pesticides? How many? Where? What about the water? What about the wildlife? What about the workers? What about the farmers? The Farm Bureau, the National Agricultural Chemicals Association, environmental groups, opposite poles fighting with each other, still fighting with each other 35 years later. I am not sure if that is a comment on organizations like mine, the industry, the process, whatever, but we are not effectively finding solutions.

Senator Lugar will remember that I participated in 1986 in negotiations between the industry and a coalition of environmental and labor and consumer organizations where we found common ground on a variety of testing issues. Much of the debate then, as it is now,

was what are the health effects of these chemicals. Because they had not been fully tested and many of them still have not been, now, as the data is coming in, I think the debate is moving to what do we do? What is the regulatory response as we are finding these adverse health effects that may result from exposure.

I think, unfortunately, for a variety of reasons, we have now moved farther apart, and we are back throwing bombs at each other. I think that is unfortunate. I am not sure there is a solution. I would like to find one.

After World War II, there were two parallel events that occurred. One was the biochemical revolution and the introduction of pesticides into American agriculture. The other was the birth of the "boomer generation" and many of us in this room are Members of that generation. We have traveled that road together and we are now all children of the chemical age, for better or for worse. I think that is the essence of the debate: for better or for worse.

There is no question that pesticides have changed the face of American agriculture. There is no question that they have increased yields, there is no question they have been good for the consumer in many respects, good for the farmer in many respects. There is a book about technology called "*The God That Limps*," and there is no question as well that there has been a down side to this introduction of chemicals into agriculture.

We now use some two billion pounds of pesticides every year in this country. In California where I live we use 500 million pounds of these poisons and they are poisons. That is about 20 pounds for every man, woman, and child in my State. They have fouled the rivers, the lakes, drinking water supplies. Over 1,000 drinking water wells in California have been closed from DBCP contamination. An EPA survey of ground water found that some 15,000 drinking water wells have been contaminated with pesticides, more than 9,000 at levels higher than EPA said were safe.

We are, I think, beginning to take some steps and I think the chemical industry is to be complemented for taking some steps to try to deal with the chemicals that leach and use them in a more constructive manner so that we can grapple with this ground water problem which is a very serious problem.

In discussing food, we focus a great deal on what is the exact health risk? Is it zero? Is it 1, 10, 100?

Is it in avocados or apples or pears or peaches or milk or meat or dairy products?

We focus too little on the generic question of what does it do to the natural environment to put billions of pounds of these chemicals every year onto the earth. Where do they go? Only about 1 percent reach the target organism. That leaves 99 percent. Some of it evaporates; some of it gets into the water.

Farmers are becoming more like chemical workers; they are being exposed to the chemicals. We still do not know what the long-term health effects are.

One new study of the boomer generation found that at least there is a reason to believe that we male members of the boomer generation are three times as likely to develop cancer, nontobacco-related cancer, as were our grandparents.

Is that from toxic chemicals? Is that from pesticides? No one can say with any certainty. They could not say 30 years ago with any certainty, and I would imagine that 30 years from now science will not tell us with certainty whether the increase in so many forms of cancer is attributable to pesticides.

Ms. Brickey indicates that we should look at the wildlife. I think that is correct. If you look at places like the Great Lakes where we are seeing waterfowl and fish—male fish becoming female, hermaphroditic; in the Everglades, alligators changing sexes, very low birth rates, behavioral disorders, birth defects; the Everglades leopard developing testicular atrophy—if it can do it to a leopard, I am going to look at it and I am going to worry.

The policy response to pesticides in 1958 was the Delaney clause. I am the lead counsel in two cases implementing the Delaney clause. One was called *Les* v. *Reilly*. It is now finally decided in the Ninth Circuit and had Delaney applied to pesticides. The other is called *California* v. *Browner*. It seeks to implement the *Les* decision across the board. I have been pleased that this administration, unlike its predecessor, has taken the Delaney clause seriously. Over the next several months the Agency will begin to actually act on pesticides that violate Delaney.

Is Delaney perfect? No, I do not believe it is. It is not a panacea, but it remains the appropriate policy response to toxic chemicals. The policy of Delaney, of prevention, the policy of slowly but surely reducing human exposure to pesticides that cause cancer and nerve damage and reproductive harm and so many other ills is the proper policy response.

For any new legislation, I think there are two goals. I almost feel like this is health care. I do not care how we get there, but there are two goals that the industry, the environmental groups, the Congress, and the public, I think, should share. One is to reduce the overall use of pesticides in agriculture over the coming years from this 2 billion pounds. Other countries are doing it around the world, and there is no reason we cannot.

And the other is to slowly phase out those chemicals that are the worst actors, many of which were developed during World War II. They have been on the market 50 years, the parathions, and the like. There are a number of chemicals that there is simply no longer any excuse to allow in our environment. If those two policy objectives can be achieved, we will go a long way to finally finding a solution to these problems.

Thank you.

Senator DASCHLE. Thank you very much, Mr. Meyerhoff. We appreciate your insight and comments this morning—this afternoon.

Senator DASCHLE. Jay Vroom, the president of the National Agricultural Chemicals Association, is next. Mr. Vroom, welcome.

STATEMENT OF JAY J. VROOM, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, WASHINGTON, DC.

Mr. VROOM. Thank you, Mr. Chairman. I too would like to commend you for holding this hearing and for the keen interest that we all know this subcommittee and the Full Committee on Agriculture and Forestry in the Senate has in the issues that are critical not only to the members of my organization that account for the

manufacture of nearly 100 percent of all the active ingredients used to protect crops in American agriculture, but, indeed to our customers, the American farmer, and our ultimate customers, the American food consumers.

I too would like to speak from the heart as my friend, Mr. Meyerhoff, has just done in a very profound way. I would like to add a little perspective to what he has just said. I agree with a great deal if not all of what you just said, Al.

Mr. MEYERHOFF. Write that down. Someone write that down.

Mr. VROOM. But I would like to add that in addition to the risks which we must manage with regard to the use of my industry's technologies in producing abundant and safe food and fiber, that we ought to also be reminded of the benefits. From my perspective, having been born in the early 1950's on a livestock farm in Illinois, I can tell you exactly what the use of technologies have meant to the productivity of corn and soybean output on my home farm.

And I think that it is pretty evident if you look at macroeconomic data available from USDA, that in my lifetime, over four decades, American agriculture has more than doubled, perhaps nearly tripled its total output. I think it has got even higher quality values than a doubling or a tripling in those 40 years, and it is doing that with 40 percent, maybe 50 percent less labor employed on the farm.

That means that people like myself and quite a few others that are in this room who grew up on farms—do not work there any more. I am not sure that I would like to go back to earning a living the way my father did in the early and mid-1950's with not so technologically intense agriculture.

We do appreciate the chance to be here. We have likewise got written testimony that we request be included in the hearing record. We also have some detailed comments on the legislation that Mr. Pryor and Mr. Lugar have cosponsored and introduced, S. 1478, that we would also like to offer for the record.

The benefits of our industry's technologies and other technologies that farmers use in concert with an ever-varying deployment of crop protection technologies were exemplified by remarks that Mr. de la Garza made at the beginning of the Domestic Operations and Nutrition Subcommittee markup of Food Safety in the House yesterday.

At that hearing the Chairman pointed out that Americans are the best fed consumers in the history of the world, spending the least amount of disposable income per family for food, and he attributed a lot of those advances to technology and I think he is right.

EPA Administrator Browner apparently agrees with that statement, in general. In June she told your Full Committee here that this country enjoys one of the safest and most affordable food supplies, and one of the most abundant in the world. I represent the industry that provides some of those important technological tools for ag production. We are proud of our contribution. We believe that this system of regulation of our industry is sound. It is an important part of our business. It is a valued part of our business. It provides predictability and continuity for the important and long-term investments that are required to stay in this business.

Mr. Lugar has one of our member companies headquartered in his home town. They just dedicated a new world headquarters and research facility. Hundreds of millions of dollars are committed to long-term research and development represented there and other places around this country.

NACA, along with 250 members of the Food Chain Coalition supports S. 1478, and we think it represents substantial compromise and progress. I think it is fair to say that all the major participants agree that Delaney does need to be reformed and we look forward to hearing more about your thoughts and the thoughts of the other witnesses about how that might be attacked. It is especially important because of the mis-information that we continue to see imposed upon the American consumer by supermarket journalism and tabloid television. It is especially important that these policy decisions, be based on sound science and not hearsay or exaggerated claims.

In that regard we are deeply concerned about a lot of misleading statements that are coming from the senior political policymakers at EPA. In statements at the National Press Club and elsewhere EPA leaders have declared that the current food safety laws tolerances are not health based. That statement and the implication that tolerances are based on agricultural convenience are benefits only to the registrant is patently untrue.

My industry is committed to reform and the process of developing new policy and new law that will make sense not only for our business but also for our customers and American food consumers and consumers around the world.

We are committed to working with you, Mr. Chairman. We look forward to working with this committee and the other committees of jurisdiction in the Congress that have a critical interest and are working hard to try to advance progress.

It is a tough issue, one that we all believe passionately in and we thank you for this opportunity to appear before you.

Senator DASCHLE. Thank you for your testimony and without objection all of the testimony that you have brought to the committee will be made a part of the record at this time.

Senator DASCHLE. Dr. Philip Landrigan is, as I said, the chairman of the committee on Pesticides in the Diets of Infants and Children for the National Research Council and we are pleased that he could be with us. Welcome.

STATEMENT OF PHILIP J. LANDRIGAN, M.D., CHAIRMAN, COMMITTEE ON PESTICIDE IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL RESEARCH COUNCIL, NEW YORK, NY

Dr. LANDRIGAN. Thank you, Mr. Chairman. I am pleased to be here and I applaud you on having called this hearing.

I am a pediatrician trained clinically in pediatrics. I spent 15 years as a commissioned officer in the U.S. Public Health Service. I have been professor of pediatrics and professor of community medicine at the Mt. Sinai School of Medicine in New York City since 1985.

I had the privilege from 1988 to 1993 to chair the Committee on Pesticides in the Diets of Infants and Children that was convened by the National Academy of Sciences under a directive from your

committee. Our charge was to examine the current pesticide regulatory system in the United States and specifically to look at whether this regulatory system provides adequate protection to children.

The major conclusion that we reached is that the regulatory system does not provide adequate protection to children. There are several reasons why we believe that the system fails. I would like to take a moment to enumerate those factors with you.

The first problem is that this current system fails to recognize that children are fundamentally different from adults. They differ from adults in two principal ways.

First of all—and this is the one that was more intuitively obvious to all of us on the committee as we started our work—is the simple fact that the children are not little adults. Children, and particularly the very youngest children, are undergoing rapid growth and development; organ systems are still not fully formed at birth. The nervous system, for example, still has a long way to go at birth. If you have ever tried to discuss philosophy with a 2-month-old, the hardware and the software are not yet there; they are still being formed. Because this development is an extraordinarily delicate process, it is highly susceptible to disruption by any one of a number of factors including chemicals, including physical agents.

An even more important difference between adults and children is the fact that the dietary exposures of people in different age groups differ absolutely enormously from each other. For example, a child under the age of 6 months consumes seven times as much water, pound per pound of body weight per day, as does an adult. These are vast differences and generally they tend to be several times greater than the biological differences between adults and children.

Unfortunately the pesticide regulatory system that has been in place for so many years does not consider these differences at all. It considers all Americans as though we were young adult males consuming the diet that is typical of a fully formed member of the species. In consequence of this regulatory oversight, little children who concentrate on a small number of foods and eat relatively vast quantities of those few foods can be quite seriously overexposed to pesticide residues in the diet if any of those few foods happen to be heavily contaminated. Our committee did spend several years running computer scenarios that laid out the dimensions of this problem. We showed quite clearly that potential for serious overexposure of children to pesticides exists.

I should emphasize—that the findings of our committee were arrived at unanimously. We had a committee that differed substantially in their scientific backgrounds, in their life experiences, and in their political points of view. Yet after 5 years of working together we reached unanimous conclusions. There was no dissent; there was no minority report.

We had a lot to say in the committee report about tolerances. We are very much concerned that the present procedure for setting pesticide tolerances in foods does not adequately protect children. Tolerances are set through a balancing process. Health concerns enter into the judgment but also economic and agricultural factors enter in.

One of the very striking documents that came into our hands as we were proceeding through our work was a letter that was sent to Senator Kennedy by Ms. Linda Fisher, then the Deputy Administrator of EPA, listing several hundred pesticides where the tolerances exceeded the so-called reference dose, the number that used to be called the acceptable daily intake for pesticides.

The committee was really quite shocked by this document. We were very much concerned that there were many pesticides allowed to be present on foods in levels that are not safe. We believe that that is a situation that needs to be remedied. We made it our very explicit conclusion that the Government must have as its clear goal in the setting of tolerances that the health of infants and children be protected.

We made a series of technical recommendations. I will not bore you with the details of them now, but they had to do with: First, better collection of food consumption data; second, better testing of pesticides for toxicity particularly better testing of toxic effects that would result from early exposure. We made recommendations about the need to consider the combined effects of pesticides that have common mechanisms of action, something that is not considered by the EPA today.

I shall stop there. Mr. Chairman, I would like my full statement entered for the record.

Senator DASCHLE. Without objection it will be made part of the record and we thank you very much, Dr. Landrigan.

Senator DASCHLE. Dr. Stephen Ziller, the vice president for Science and Technology of the Grocery Manufacturers of America. Dr. Ziller, thank you for coming. Please proceed.

STATEMENT OF STEPHEN A. ZILLER, Ph.D., VICE PRESIDENT FOR SCIENCE AND TECHNOLOGY, GROCERY MANUFACTURERS OF AMERICA, INC., WASHINGTON, DC.

Mr. ZILLER. Thank you, Mr. Chairman. I have submitted a more detailed statement which I would like to have put in the record.

Senator DASCHLE. Without objection, it will be made a part of the record.

Mr. ZILLER. I want to thank you and the Members of the subcommittee for inviting me to speak.

I am the vice president for Science and Technology at the Grocery Manufacturers of America. This group is an 85-year-old national trade association comprised of more than 130 manufacturers and companies——

Senator DASCHLE. Dr. Ziller, would you mind pulling the microphone close to you? Thank you.

Mr. ZILLER. GMA members employ over 2.5 million people and our members produce more than 85 percent of the packaged food sold at retail in the United States. For almost two decades GMA has supported the concept of revising the statutory provisions governing Federal regulation of pesticides used in the production of food. That support has, of course, been conditioned upon new legislative provisions that would strike an appropriate balance between preserving an abundant food supply and protecting against unsafe pesticide residues.

My testimony today will deal with these several general principles that GMA believes are essential to any successful legislative approach to revise the current statutes relating to Federal regulation of pesticide residues in foods. Due to a time constraint I will briefly describe some of those today.

First, national uniformity. It is essential that any legislation establish a single national policy for the regulation of pesticides used in food production. We cannot tolerate a system of 50 different pesticide laws. Any legislation lacking national uniformity is not acceptable to GMA and its members.

Second, safety of pesticides. New legislation should require pesticide tolerances to be established at a level that will adequately protect the public health. We support the use of reasonable risk assessment procedures to assure that there is a negligible risk. It is inappropriate and scientifically unacceptable to establish detailed rules for safety assessment in legislation because science changes so quickly and the legislation simply cannot keep up with it.

Third, benefits of pesticides. Any new legislation must reflect the fact that pesticides play a major role in the production of a safe and wholesome food supply and thus provide substantial benefits to the American public. Pesticides control disease and preserve an adequate and affordable food supply.

Fourth, the food pipeline. The presence of pesticides in the food chain occurs not at a single point in time but over many years. It is possible to stop using a pesticide or to reduce pesticide use on the farm at any particular point in time, but nothing can be done to remove or alter the pesticide residues that exist from prior legitimate use on food that has already entered the food pipeline.

Appropriate legislation must therefore reflect that food containing pesticide residues that were lawful at the time of use must remain lawful throughout the subsequent life of that food unless new information demonstrates a serious health hazard.

Fifth, enforcement. Both EPA and FDA currently have extraordinarily strong enforcement authority that is more than adequate to implement any new pesticide legislation. New enforcement authority for EPA and FDA will preclude industry support on legislation.

Citizen suits and whistleblower provisions are extraneous to pesticide legislation and cannot be justified. Any legislation with enforcement provisions of these types will be vigorously opposed.

It is important to pare down pesticide legislation to the bare essentials, if it is to be supported by the food industry.

The principles mentioned today and those included in the written statement establish the GMA position on these matters. The legislation introduced by Representative Lehman and Senators Pryor and Lugar here today meet these general principles, and we support that legislation.

I would note that H.R. 1627 has the support of 222 Members of Congress, and was marked up yesterday in the House Domestic Operations and Nutrition Subcommittee of the House Agricultural Committee.

The legislation recently introduced by the administration violates virtually all of these principles, and we strongly oppose it.

Thank you.

Senator DASCHLE. Thank you, Dr. Ziller.

Our next witness is Ms. Juanita Duggan, the senior vice president of Government Affairs for the National Food Processors Association.

Ms. Duggan, thank you for being here.

STATEMENT OF JUANITA DUGGAN, SENIOR VICE PRESIDENT, GOVERNMENT AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION, WASHINGTON, DC.

Ms. DUGGAN. Thank you, Mr. Chairman.

NFPA is a food trade association with a science and technical background, and we maintain three state-of-the-art food science laboratories around the country.

Senator DASCHLE. I am not sure the microphone is picking you up. You may just want to pull it a little bit closer to you.

Ms. DUGGAN. Is that better?

Senator DASCHLE. Yes, I think so.

Ms. DUGGAN. We represent many of the fruit and vegetable processors in the United States, and therefore we have a tremendous interest in food safety procedures and pesticide regulatory standards at EPA.

We are very happy to be here today to talk about some of the important pesticide policy decisions that are facing the EPA.

The food processing industry strongly supports the development of effective alternatives to pesticides, but we would note that even with ongoing efforts to reduce the pesticide use and to develop alternatives to pesticides, pesticides will be necessary for the production of an adequate, wholesome, and nutritious food supply for the time being.

NFPA has long supported statutory changes to the Food, Drug, and Cosmetic Act and to FIFRA to reform the Delaney clause to establish a uniform standard for pesticide residues in both raw and processed foods and to give EPA sufficient authority to take into account best scientific information when making those tolerance decisions.

We have been hopeful that this would be the Congress where we could produce a piece of pesticide reform legislation. We are a bit dismayed that we are here in the summer of the second session, and we have made very little progress to date on moving a piece of legislation. We are encouraged by the Ag Committee's interest today, and hopefully we will be able to move forward as the House subcommittee did yesterday.

The administration has recently released its own proposals, and you heard from Dr. Ziller that the food industry has many concerns about those proposals. I would like to discuss why NFPA supports other bills, namely S. 1478 introduced by Mr. Pryor and Mr. Lugar.

We appreciate the fact that the administration recognizes that the Delaney clause is outdated and must be reformed, but their bill would restrict, rather than enhance, EPA's ability to apply the best scientific in making tolerance decisions.

We also believe that the administration's bill goes far beyond what is needed to reform the Delaney clause. It is a FIFRA reform measure, an enforcement piece of legislation, that includes many things that are not necessary to Delaney reform.

It would eliminate the consideration of benefits. It would revise most major FIFRA procedures to reduce public participation rights and scientific review requirements. It would authorize multiple additional enforcement powers to both EPA and FDA, and it would authorize citizen suits in a variety of contexts.

We do not believe there is any demonstrated need for such a total overhaul of FIFRA.

The administration has argued that immediate legislative action is needed to avoid the potential crisis that has been created by the Ninth Circuit Court Decision that Mr. Meyerhoff referred to, the *Les* v. *Reilly* decision that was handed down in 1992.

The administration has stated that unless immediate legislative changes are made, the Agency will have no choice but to revoke tolerances for a large number of valuable pesticides with serious adverse consequences for both agriculture and the food processing industry.

We maintain, however, that the Agency's hands are not tied by the *Les* v. *Reilly* decision. The potential devastating loss of agricultural pesticides that are threatened by EPA are not necessarily a result of the *Les* v. *Reilly* decision, but are instead the result of EPA's concentration and coordination policies. The policies are an EPA invention, they were never properly adopted as regulation, and we believe they should be abandoned.

In September of 1992, NFPA filed a petition, along with several other groups—some of them are represented at this table—in which we urged EPA to rescind the concentration and coordination policies and no longer require separate 409 tolerances for pesticides and processed foods.

Basically we have asked them to follow the language and the intent of the flow-through provision of the Food, Drug, and Cosmetic Act, which would provide that a pesticide residue in a processed food, when ready to eat—which is a key concept—is lawful, as long as the residue is not greater than the tolerance for the raw commodity from which the processed food was made.

The petition demonstrates that there is no sound legal or public policy basis for EPA to continue the concentration and coordination policies, and we believe that EPA should not be permitted to perpetrate these policies to create an artificial pesticide crisis in order to get an unnecessary FIFRA bill.

Moreover, the Administration bill does not address several issues that are of critical importance to us, one being national uniformity, which you just heard about, and it does eliminate the consideration of benefits, which we believe to be a key concept in any meaningful reform of FIFRA.

In short, we strongly support S. 1478. We believe that it is the best vehicle to pursue for pesticide reform in this Congress. It would streamline the cancellation and suspension processes. It would establish a consistent negligible standard for raw and processed foods, and it would assure appropriate consideration of benefits and national uniformity for tolerances.

I would like to add that S. 1478 also contains specific provisions which we strongly support that would require EPA to implement the recommendations described within the recent National Academy of Sciences report on pesticides in the diets of infants and chil-

dren. This is the most complete response of any bill before the Congress to the NAS recommendations. It simply directs the administrator of EPA to implement all of those recommendations. So we are very strongly supportive of that.

Yesterday, the House subcommittee on—what is generally referred to as the Donut Subcommittee—Domestic Operations and Nutrition marked up H.R. 1627, the Pryor-Lugar Companion bill, and we look forward to similar action here on the Senate side.

That concludes my statement. I have a longer statement that I would like for you to include in the record.

Senator DASCHLE. Thank you. Without objection, it will be made part of the record.

Ms. DUGGAN. Thank you.

Senator DASCHLE. Mr. Jim Bender is a farmer and author of the book, "*Future Harvest.*" He is from Weeping Water, NE.

How big is Weeping Water, Mr. Bender?

Mr. BENDER. 1,000 people.

Senator DASCHLE. 1,000.

Senator PRYOR. At least it is not Whitewater.

[Laughter.]

Senator DASCHLE. Whitewater is weeping water.

[Laughter.]

Senator DASCHLE. Please proceed. With that editorial comment, we will take your testimony.

STATEMENT OF JIM BENDER, FARMER AND AUTHOR OF THE BOOK "FUTURE HARVEST," WEEPING WATER, NE

Mr. BENDER. Mr. Chairman, and Members of the subcommittee, I appreciate the opportunity to participate in this hearing this afternoon.

A central issue for pesticide policy concerns what American agriculture would be like with only minimal reliance upon chemical pesticides. There are several ways to pursue this subject.

An obvious one would be to study contemporary farms in which pesticides have been minimized or eliminated. Especially useful would be farms that are otherwise typical. By "typical," I mean farms that have developed with their fair share of agronomic challenges, do not rely upon inputs unavailable to agriculture in general, and have not received grants or other special funding.

Our farm comes to mind. It has been free of pesticides on all the land since 1980 and certified organic since 1990. It is a four-generation family farm, 642 acres, located between Lincoln and Omaha at the very western edge of the nonirrigated Corn Belt, which results in moisture extremes.

Virtually all of the farm has been designated as potentially highly erodible by the Soil Conservation Service. The topsoil on many of the hillsides of the farm is thin as a result of profound soil erosion during the first decades of this century.

How does this farm perform? In many ways, it is highly productive and conserving of resources. It competes with our chemical-based neighbors in yields. It is exceptionally resilient in years with difficult weather or economic conditions.

We receive visitors and agricultural researchers each year, who are complimentary about weed control. In addition, aggressive, multifaceted soil conservation program coincides well with the pesticide-free cropping.

It provided employment opportunities for local youth.

And finally while the farm has enjoyed special organic markets the last 2 years, prior to that time, mere conventional agricultural markets paid for land, large modern machinery, buildings, and other infrastructure.

The success of farms such as ours gives rise to a question: If these farms effectively address so many problems and offer other advantages, why, then, do our neighbors continue to farm in ways heavily reliant upon chemical pesticides?

That is a question with no easy answer. A starting point, however, is the ways that Federal agricultural policy influences agricultural practice. There are many examples.

Policy penalizes crop rotations that are essential to low and no-pesticide farming. It generally does not orient research to support this kind of farming. Federal policy on highly erodible farmland places high priority on pesticide-based cropping practices. Policy contributes to overly optimistic views of pesticide risk. Current policies permit agricultural benefits to override health and safety concerns.

These things and others influence agricultural practice. They also begin to explain why farms such as ours are isolated, with so little influence.

In conclusion, there are currently low and no-pesticide agricultural systems creating solutions to basic agricultural problems. Their effectiveness will continue to be limited until Congress removes existing obstacles.

Thank you.

Senator DASCHLE. Thank you, Mr. Bender.

Our final witness is the president of the Pennsylvania Farm Bureau. He is Mr. Keith Eckel from Clarks Summit, PA.

Welcome, Mr. Eckel.

STATEMENT OF KEITH W. ECKEL, FARMER AND PRESIDENT OF THE PENNSYLVANIA FARM BUREAU FEDERATION, CLARKS SUMMIT, PA

Mr. ECKEL. Thank you, Senator, Mr. Chairman—Senators; my name is Keith Eckel. I am president of the Pennsylvania Farm Bureau, testifying on behalf of the American Farm Bureau, and I am a farmer involved in vegetable and grain production in Lackawanna County in Clarks Summit, PA, and we use a variety of technologies in our production, and we absolutely have been involved in reductions of pesticides, as have most farmers been, in the operations of their businesses because of the economic incentives when that is feasible.

Mr. Meyerhoff indicated that there had not been a lot of change in the debate. There has been some change in agriculture.

Part of the written testimony that I would ask to be made part of the record today, as well as the testimony that we would submit on behalf of the Minor Crop Farmer Alliance—and we would ask that you would accept that.

Senator DASCHLE. Without objection, it will be made part of the record.

Mr. ECKEL. One of the changes is, since 1976, in the written testimony that we provide is that pesticide use has declined in real pounds from 1976 to 1993. So, perception is not reality, and uses have declined.

There is another occurrence that has occurred, and that is that the cost, as a basis of income for purchasing food, has declined. In fact, in the last 10 years, the average consumer has declined from expending 16 percent of his disposable income for food to less than 11 percent.

The National Health Discussion was mentioned in the testimony today. I would point out to you that we are studying a "national health crisis," in quotes, because costs in the last 8 years have escalated from 9 to 14 percent. If it was not for agriculture's increased productivity and lower costs, especially for low-income American consumers, the health care crisis would be much worse.

So you readily recognize that I am not an agricultural apologist. However, I am an advocate. Also, I am proud to be part of an industry that has contributed as much to this country and its consumers as we have. We absolutely cannot continue to take that for granted.

In my own operation, we have reduced pesticides with integrated pest management. With new management techniques, with a use of a variety of pesticides, and sometimes there nonuse, it requires intensified knowledge, as I am sure Mr. Bender would testify to, as we recognize pests, as we determine the thresholds for the use of insecticides, and we use a broadbased supply of various products to control the pests that we are dealing with.

One of my strong concerns in the proposals that we are looking at is that in nature they seem to be punitive rather than friendly, punitive in the sense that who would want to be an applicator, a commercial applicator of pesticides, if the first offense is going to be considered criminal in nature with penalties up to $25,000 for use? Who is going to be encouraged to enter into that field and bring more technology, rather than less, to the application on our farms?

And so that whole section has concern for us as far as the punitiveness of it. Civil actions indicating that perhaps the EPA and the Federal Government is unable to enforce their own regulations would indicate to me that what we are attempting to encourage is people without technical knowledge coming and looking at our own farms and determining whether or not those practices are proper or right, filing complaints, and causing us to expend untold dollars in legal expenses as we defend ourselves in proper actions.

Minor-use pesticides,—let me give you just one economical example—and this is what puzzles me with food safety.

I produce fresh market tomatoes in my own operation, and we use herbicides in that production. One of the herbicides that we use for nutgrass control is Tillam. One of the problems with Tillam is that it does not have any control for a new weed problem that we have called nightshade.

There is a product on the market today, legal for most major crops, also legal incidentally for string beans, legal for use in Can-

ada on tomatoes that are shipped into this country and produced, called Dual. The cost of that product—and that controls nightshade—the cost of that product is $15-an-acre in comparison to $40-an-acre for the Tillam.

Because we have created the onerous system for re-registering pesticides and the uncertainty in our system for whether or not they are going to be removed—and under the new system that is proposed by the administration, we would be able to remove pesticides without even the proper due process of the registrant—there is absolutely no encouragement to add the minor-use of tomatoes for Dual. So one singular item costs me $25-per-acre, but adds additional cost to every consumer in this country.

I see the red light is on, yet, I want to speak; if you will indulge me one moment to the issue of health.

The first step to good health in this country or around the world is proper nutrition. To ignore the benefits that are afforded to us by our technology today is to bury our heads in the sand and not recognize the immense benefit to the low-income people in this Nation and those in developing Nations around the world who partake of the bounty of American farmers' production as a result of our technology.

Gentlemen, we have a major responsibility here, not to reinvent the wheel, but to create a system that encourages the development of new and safe technologies that provide an adequate and reasonable food supply for this Nation and the rest of the world and also maintain our environmental sensitivity.

We, today, are producing on the same number of cultivated acres that we were in 1900, not in small part due to the fact that technology, part of which is pesticides, has allowed us to enhance that and improve the wildlife habitat instead of destroy it.

Gentlemen, I appreciate the opportunity to testify before the committee. I look forward to your questions. I am confident that you will work together to give us a bill that will maintain the confidence of American farmers as they face a very uncertain future.

Senator DASCHLE. Thank you, Mr. Eckel, for your comments.

We appreciate the testimony and the contribution made by all of our witnesses this afternoon.

We like to encourage a good healthy discussion at these hearings, and that is why we have set it up as we have. We appreciated very much your opening remarks, but we would like very much now to enter into a good discussion about a number of the issues that have already been raised in testimony and in our opening remarks.

Let me again invite Senator Pryor to make any comments. He had indicated that he perhaps would wait until the end of testimony before he said anything. If he has some remarks to make at this time, I would invite him to do so.

Senator PRYOR. Yes, please. I would like to start our discussion and then maybe I could enter into it a little later.

Senator DASCHLE. OK.

Senator PRYOR. It is not that I am afraid of these people or anything.

[Laughter.]

Senator PRYOR. I have enjoyed hearing the various statements, and I think it is very instructive to listen a little further.

Senator PRYOR. Thank you, Mr. Chairman.

Senator DASCHLE. Thank you, Senator Pryor.

Let me just begin. I have a lot of questions, and I would encourage all of our Colleagues to interject here.

Let us go back to the Delaney clause for just a minute. I am not sure I understand the collective perspective of this group. I would be interested if we could, maybe beginning with Mr. Meyerhoff, talk about whether it is the view of this panel that EPA specifically needs more regulatory authority in order to regulate the Delaney clause, given the rulings, especially the *Les* v. *Reilly* ruling, or is it your view that EPA has the ability to do it unilaterally without additional authorization?

Mr. Meyerhoff?

Mr. MEYERHOFF. Well, Jay—Jay Vroom—indicated at the beginning of his testimony that he agreed with almost everything I said, so——

Mr. VROOM. Almost.

Mr. MEYERHOFF [continuing]. I think I could speak for both of us, perhaps.

Mr. VROOM. Almost.

[Laughter.]

Mr. MEYERHOFF. The Delaney clause, the essential premise of the Delaney clause, is that of a substance induces cancer in man or animal, its presence in processed foods is not permitted. That was because of an amendment in 1958 dealing with processed foods.

The conflict that the NAS pointed to in its 1987 report on the Delaney clause is that we have two fundamentally inconsistent standards between processed foods and raw commodities.

Section 408, which regulates raw commodities, is, as Dr. Landrigan indicated, a cost-benefit standard.

Right now, I think the administration—we have had numerous meetings, the White House and at EPA, about how Delaney will be implemented. Carol Browner, at the beginning of this administration, stated for the public record that the administration supported changes in the Delaney clause, but only if those changes would improve protection of public health.

If no changes were forthcoming, however, the administration indicated its intention to obey the law as written. That is what I believe they are now about to do, and I believe that is long overdue.

They have not identified 35 or more pesticides used on roughly 100 crops where their current data indicates that the chemicals in question, chemicals like Alachlor and Captan and DDVP, the EDBC—EBDC—EB—ethylene diborochloride——

[Laughter.]

Mr. MEYERHOFF [continuing]. Are violative of Delaney.

Senator DASCHLE. But I guess what I am asking—and you are giving a good answer—but just to——

Mr. MEYERHOFF. You want to know whether or not——

Senator DASCHLE. Well, is it necessary, or is it desirable?

Mr. MEYERHOFF. Delaney itself?

Senator DASCHLE. No, no. Is additional clarification in law having to do with the Delaney clause a requirement, or is it simply desirable?

Mr. MEYERHOFF. Jay and I may disagree on this one.

The current law—we are quite content with the current law for processed foods. Delaney is the most health-protective statute adopted anywhere in the world.

Senator DASCHLE. But does EPA have the ability to respond with some flexibility to the Delaney clause, given current interpretation?

Mr. MEYERHOFF. In our view, after the Ninth Circuit Decision in *Les* v. *Reilly,* they do not. In fact, that was the unequivocal holding of the court.

The administration and EPA at the time asserted that they had the right to find a *de minimis* risk exception to Delaney. That was rejected by a court made up of three Judges, somewhat like this debate—one Judge from the Eisenhower administration, one Judge from the Reagan administration, and one Judge from the Carter administration.

They reached agreement that Delaney was absolute and prohibited pesticides that induce cancer and that concentrate from being present in processed foods. Absent legislative change, EPA now have to obey that law as written.

Senator DASCHLE. But you say in spite of that ruling you would not be opposed to keeping the Delaney clause just as it is now authorized?

Mr. MEYERHOFF. That is correct. We do not believe that Delaney is an absolute panacea. It does not deal with a variety of other end points like nerve damage and reproductive failure, and it particularly does not deal with the cost-benefit standard that is in 408, and we would and do support legislation that would replace Delaney with another approach, the one that I talked about in my testimony. If not, we are quite willing to work together with the administration to ensure they obey the law.

Senator DASCHLE. Mr. Vroom?

Mr. VROOM. Well, again, I think we agree that there are two answers.

We might disagree with regard to the detail of what those two answers or alternatives would be, and as we see it, the EPA has ignored both statutory as well as regulatory fundamentals in taking it to the point where they have taken the execution of the strict interpretation of Delaney in the *Les* v. *Reilly* case. Also, in my written testimony there are six major points enumerated and identified in great detail.

I think one of the most important points—is the "coordination policy" with regard to 408 and 409 tolerances and the intensive scientific knowledge about these particular compounds and the dozens of other pesticides that EPA has also identified on a potential Delaney target list beyond the seven in the *Les* v. *Reilly* case. They are ignoring the scientific evidence of what fits the definition of "induces cancer" as defined explicitly in the Federal Food, Drug, and Cosmetic Act as it currently is on the books.

They ignore the differences between human species and laboratory animal species. When tumors occur in certain laboratory spe-

cies, organs that have no parallel to human species, then there ought to be some kind of accepted scientific flexibility to make an interpretation about what induces cancer in the translation to humans.

Those factors have been totally ignored by the Agency, and we think they are incorrect; in some specific cases, we believe they are illegal.

Given the strict interpretation of Delaney, based on the way the Agency has indicated it is heading so far, we believe that the Congress will be in a position to have to act in order to avert the so-called train wreck.

On the other hand, we believe that the Agency does possess the flexibilities within the law to take a different track, and we believe that they may have the opportunity to consider those options in the very near future.

Ms. DUGGAN. Senator Daschle?

Senator DASCHLE. Ms. Duggan?

Ms. DUGGAN. These are the issues that are found within the NFPA petition. We are trying to take a step back in the wake of the *Les* v. *Reilly* decision and look at the statute from a *de novo* perspective, and our viewpoint is that Congress never really intended for pesticide residues in processed foods to be treated as food additives in the first place. EPA sort of backed into this policy over the course of about 20 years by trying to interpret a *de minimis* policy out of Delaney which the court has now said they cannot do. They backed into this by developing these two policies, what is referred to as the concentration and the coordination policies.

And the issue of whether or not pesticide residues concentrate in processed foods above the raw product tolerances is a very controversial one.

Yet, we do not believe that, number one, there is a whole lot of evidence that they do concentrate above the raw product tolerance, and moreover that EPA should be looking at that on a ready-to-eat basis, which they do not do right now. EPA makes these determinations on commodities such as flour and tomato paste, and people do not sit down to meals of tomato paste and flour.

Mr. MEYERHOFF. I do, actually.

Ms. DUGGAN. You do?

Mr. MEYERHOFF. It is quite a good snack.

[Laughter.]

Ms. DUGGAN. OK.

Mr. MEYERHOFF. It is just very nutritious.

Ms. DUGGAN. It sounds great. I will have dinner with you sometime.

[Laughter.]

Ms. DUGGAN. But they have the flexibility to make changes like that in the way they decide if they need a 409 tolerance in the first place. Not once have they set a 409 tolerance, does the Delaney clause apply or not, but how do you get into 409? What policies draw you into 409 in the first place?

The NFPA petition sets out a legal pathway under the current statute that would allow them to avoid the most devastating potential that would be the result of the *Les* v. *Reilly* decision.

That being said, the NFPA also believes that the only way out of this paradox that the NAS described years ago is to reform the law: the Delaney clause is outmoded; it is antiquated. Approving the NFPA petition and establishing those regulatory policies would be a partial fix. You have to have a change in the law to dispense with this whole notion that zero risk a possibility in today's world. Science has moved way beyond that.

So we have a strong interest in trying to develop a policy in the law, in a pesticide reform law, that would give us negligible risk authority and that would avoid creating arbitrary and capricious standards that are very similar to what the Delaney clause was in the first place.

We are very concerned that if we do something very restrictive and arbitrary, we will find ourselves in the next 10 years with a new Delaney clause, and that is why we strongly support the negligible risk policies that are in S. 1478 as opposed to the more prescriptive approaches that freeze today's science into the statute. We are very, very concerned about that.

Senator DASCHLE. There appears to be unanimity that modifying the Delaney clause is either something we could support or at least not oppose. I think that is—is that an accurate statement with everybody at the table?

Mr. ECKEL. Senator, that is correct.

Senator DASCHLE. Well, let us talk a little bit, then, about what we define as negligible risk. As I understand it, there appears to be sort of a consensus that we can achieve a negligible risk standard for pesticide residues, even for carcinogens, that regulators and environmentalists and processors and farmers all are somewhat in concert with regard to their confidence about determining that standard. Is that accurate?

Ms. DUGGAN. I think there is a——

Dr. LANDRIGAN. Senator, could I speak to that?

Senator DASCHLE. Let us do it all at once.

[Laughter.]

Dr. LANDRIGAN. Four-part harmony.

Senator DASCHLE. Go ahead.

Dr. LANDRIGAN. I think that in theory it might be possible, but we have to recognize that there are some profound practical limitations.

Our committee from the NAS was silent on the issue of Delaney versus some alternative to Delaney. It was not within our charge to express an opinion on that very important issue, and we did not.

What we did observe—and there is simply no question about this—is that there are great gaps in our knowledge today about the hazards of pesticides to the American public. These gaps are especially great when it comes to understanding the effects of pesticides on children.

One sort of study that has been done for almost no pesticides is a study in which your experimental animals of some particular species, like rats, would be exposed in early life to a pesticide and then

allowed to live for their normal life span, which is several years, depending on the species. The end point would be to see what happened to the animals at the end of their lives.

This is a situation that is totally analogous to exposing an infant to a pesticide and then waiting 75 years to observe effects until the infant grows into old age.

In the absence of that sort of testing—and it has not been done, except for very few chemicals—we are much flying blind when we talk about developing very sophisticated paradigms for risk assessment. Sure, we can come up with lovely mathematics and lay out beautiful equations. EPA is skilled at that.

However, the problem is that if the data that are going into those equations are faulty and if many, many datapoints are simply absent, then the exercise is a gamble. That is something we must bear in mind as we talk about this subject.

Sure, science has advanced, as several of the witnesses around this table have said. We know more about toxic effects than we did in the past. Yet, at the same time, even as we know more, we know there is more that we do not know; 30 or 40 years ago, most of the concern about pesticides concerned cancer. Cancer, of course, is the only endpoint that is mentioned in Delaney.

Today we know from laboratory testing that chemicals can cause chronic damage to the nervous system. There is no proof, but there certainly is a lot of suspicion that some cases of chronic neurologic diseases like Parkinson's disease might, in some cases, be caused by chemical exposures. We will probably have better information on that in a few years.

Reproductive problems have been hinted at. The evidence has been elusive because the experiments are hard to do. Yet, anybody who says that there is no risk of reproducing damage from pesticides is being rash, in my opinion.

Senator DASCHLE. How do we define—I mean—I think we can go on at some length about the hazards of negligible risk is, we fail to appreciate that negligible risk is still risk. The question is, "How do we define 'negligible risk', and how could we achieve a consensus on that definition?"

I sense that there is a belief that a consensus may be possible, but I am not sure that I am satisfied that there is a consensus even at this table. So if there is not a consensus at this table, how would there be a consensus outside the room?

Carolyn?

Ms. BRICKEY. I think this is a very difficult issue, Mr. Chairman, and you have, as usual, come to the heart of the problem.

I think that there is a great deal of concern on the part of the organizations that I work with about the use of negligible risk as confronted through the process of risk assessment. There are a lot of unknowns about some of these chemicals, and we do have a lot of years for these chronic health effects to take effect before we know how serious they are.

I think before any kind of system like that could be acceptable, there would have to be some severe limitations and safeguards built into it.

The regulatory experience at EPA has also not been as positive as some of us in this room would like it to have been. EPA has been moving very slowly in looking at these old chemicals.

As you know, this committee enacted legislation in 1988 telling EPA to reexamine hundreds of old chemicals by 1997.

Mr. Chairman, EPA is not going to meet this deadline. EPA will tell you that. There are lots of problems, including resources, that have slowed the progress down.

On the other hand, there are a lot of really serious concerns about how you could possibly replace the Delaney clause as it applies to processed food and build enough safeguards in to protect people from these other health effects. It is very difficult.

Senator DASCHLE. Well, somebody come forth with their definition. Let us work on a definition here.

Mr. VROOM. Mr. Chairman?

Senator DASCHLE. Yes, Mr. Vroom.

Mr. VROOM. We have referenced the National Academy reports twice here—one, Dr. Landrigan's report on infants and children and also the Delaney paradox report of the late 1980's.

Also in 1983 the Academy issued a report at the request of Congress where they focused on the question of risk assessment in general, and that has become a bit of a Bible in terms of risk assessment reference. I think an important point to lift out of that for the benefit of this discussion is that they pointed out in that report, as I recall, that there should be a separation between risk assessment and risk management.

Now risk assessment is something that Dr. Landrigan and his Colleagues in the scientific community, from a variety of different scientific disciplines, are always perfecting and attempting to advance every day in the laboratory and in debate, healthy debate, amongst themselves, and it is something that I doubt that those of us in the lay world really can fully understand or comprehend on a day-to-day basis.

However, risk management is something that Congress and the EPA implement and that Congress now has an opportunity, with the potential of Delaney reform, not only for the benefit of agriculture but many other industries as well, to take a hard look at.

I would suggest that the underlying carcinogenic threshold is one in a million—that is what the Delaney paradox report referenced.

I think all of us, at least on my side of the issue, would believe that it would be incorrect to write "one in a million" into the Federal statute, because risk assessment is changing all the time, and the use of that particular mathematical equation approach could be vastly different in 5 to 10 years from now than it is today. It could be report language and is currently the reference threshold that EPA uses in establishing tolerances not applied to 409 processed food.

Senator DASCHLE. Mr. Bender? Let me ask Mr. Bender for a comment.

Mr. BENDER. Thank you, Mr. Chairman. Before we finalize our definition, would you accept one more criticism?

Senator DASCHLE. Absolutely.

Mr. BENDER. Thank you. We have been focusing on the problem of measuring risk, and that is a very serious problem associated with this mode of risk assessment.

On the other hand, I think another is that the negligible risk standard focuses only on probability of risk. When we think about risk assessment, there are other dimensions, such as, for example, whether it is equitably incurred, voluntarily incurred, how devastating the risk would be if it were incurred. This focuses on one sole aspect of the problem of risk.

Senator DASCHLE. Good point. Dr. Meyerhoff?

Mr. MEYERHOFF. Just, Mister. I do not think this is a legal definition. A policy or ethical definition, to me, is an involuntary and unnecessary exposure to a toxic chemical, and that if you can, through an informed public policy, eliminate or reduce that exposure wherever you can, you should do so.

And I think the example I would point to—I was just sitting here thinking about it—one of the great success stories, in my opinion, in environmental law and in public health over the last 20 years has been lead. We have not won that battle, quite clearly. As the report that was released this week indicated, lead levels in human blood are down dramatically, and that is because the Congress and the Government and the courts, in enforcing those laws, have taken steps to eliminate lead in gasoline and a lot of other exposures to lead.

Now we still have a lot of problems, particularly in the inner city, with lead. We have dealt with at least the initial problem of lead poisoning in the society—and Dr. Landrigan is one of the world's experts on lead—by reducing those kinds of exposures.

And I think as he was also indicting, we cannot simply focus on cancer. Cancer is a very serious problem. One out eight women in this country will develop breast cancer in her lifetime. It is something we have to look at hard, why that is.

Neurotoxicity from these chemicals and other adverse effects are perhaps of more importance. Look at what is happening to the natural environment. These are chemicals that are a problem beyond how much is in food. We have been debating for 30 years which number should we put on this food, this chemical, that food, that chemical.

The reality of life is, we are exposed to a multiplicity of chemicals. There are over 300 active ingredients alone of pesticides. There are some 1200 poorly examined inert ingredients. I think it is a fool's errand in a long-term policy to simply try to say what precise risk for each one of these substances is, irrespective of what their combination is, in every food, set those numbers, and then walk away like we have solved the problem. We have not.

Ms. DUGGAN. If I could make a comment?

Senator DASCHLE. Yes, Ms. Duggan?

Ms. DUGGAN. What Mr. Meyerhoff brings up here is specifically one of the reasons why the food industry was very supportive of the recommendations in the NAS study for infants and children, because we strongly believe that the data gaps are very wide in the way that the Government is able to calculate exposure. There are many, many things we do not know, and we need to direct EPA to fill those data gaps, so that exposure assumptions can be based on

actual exposure as opposed to these wild guesses that are overly conservative that torque the picture of risk sometimes by many orders of magnitude.

The more information we have, the better the risk assessment is going to be. It is going to be very expensive to collect the kind of data that is recommended by the NAS. However, this debate is never going to go away until we do so.

NFPA has been maintaining for many, many years one of the largest pesticide residue databases in the country, possibly even the world, because we want to know what the picture is of the actual residues that are out in the marketplace in the products that our members produce.

And our data is entirely consistent with FDA's data. It is entirely consistent with the State of California's data, which also does an extensive amount of testing in the marketplace, and we have found, you know, 98 percent of the food out there has no residues, no detectable residues whatsoever, and when you do have detects, they are so far below tolerance that they are irrelevant.

Mr. MEYERHOFF. What was the source of the 98 percent—I am just curious—from California?

Ms. DUGGAN. That is the NFPA database. It may not be the specific number. I can provide that for the committee. Yet, it is very, very consistent across the board—the NFPA, the FDA, and California—and it is in the high 90's where there are no detects.

Mr. MEYERHOFF. No residues at all?

Ms. DUGGAN. No detects, no detects.

Mr. MEYERHOFF. I believe—I think the data is closer to 50 percent.

Ms. DUGGAN. Multiple—no, no, no.

Mr. MEYERHOFF. The data I am familiar with.

Ms. DUGGAN. No. It is way up in the high 90's.

Senator DASCHLE. Well, let us submit that for the record.

Mr. MEYERHOFF. That would surprise me.

Senator DASCHLE. You think it is closer to 50?

Mr. MEYERHOFF. Every market basket survey I am aware of—FDA and CDFA's market basket data of where they found residues—has been 40, 50 percent. So the fact that it would be more than 90 percent with no residue at all would greatly surprise me.

Ms. DUGGAN. Are you talking about detects or the level of detect?

Mr. MEYERHOFF. No, you said—I believe you said—I believe the witness said that 90 percent or more of the food had no detectable residues of pesticides.

Ms. DUGGAN. Yes, that is our information, and I will be happy to provide that for the record. The FDA, NFPA, and the State of California databases are all perfectly consistent, within a few points of each other. We are not going to——

Mr. VROOM. Could that have been residues above tolerance? Is that what you——

Senator DASCHLE. You mean illegal residues.

Ms. DUGGAN. Yes, illegal residues.

Mr. VROOM. That is a fundamentally different——

Senator DASCHLE. Aha! We are making progress.

I know that Senator Pryor has another engagement that he needs to be getting on to.

Senator PRYOR. Thank you, Mr. Chairman.

First, I want to say, Mr. Chairman, I did not want to come to this meeting this afternoon. I have been to too many meetings, as has Senator Daschle, in the last 15 years at this table in this room. When we left, there was blood all over the table and all over the floor, and everyone left mad, and we did not speak again for another 2 or 3 years.

[Laughter.]

Senator PRYOR. And the media all wrote about the white hats and the black hats. They characterized various parties and groups in that way.

Now I felt it to be very unfair. Sometime back when I was asked to be a part of attempting to move out into the middle some way some legislation and to try to find a solution to the Delaney clause—and I think most of our people here seem to think that the Delaney clause needs some attention one way or the other—I was very reticent to do it.

However, I want to say this to you, Mr. Chairman, I think that this has been one of the more constructive meetings that I have been to in a long time. It is not one of those typical formal meetings when the Senators and the politicians get up there and talk a long time. I think it has been an exchange. I think we have just seen a situation here were we are looking at definitions and characterizations, and at least we are coming to terms with some of the terminology. I think that, in itself, is good.

Finally, I would like to say that I think that this committee has attempted and is attempting—I know that Senator Lugar and myself are—we are attempting to find some solutions to the problems that we face, not based on political rhetoric, but based on scientific evidence, trying to find something based on fact. That is what we are attempting.

We are not attempting to take the food chain, the greatest food chain that civilization has ever known, and to contaminate it. We are not doing that. We want to keep it the best and the cleanest and the safest.

Yet, we do think that we have based our proposal on what we thought, Dr. Landrigan, was many of the recommendations by the National Academy of Sciences and the studies that you have completed and that we rely on. This is kind of where we are going from.

Also, I just wanted you to know, as our participants, kind of where Senator Lugar and I are coming from. This meeting, I think, has been extremely helpful to me. We ought to do it again sometime.

[Laughter.]

Senator PRYOR. Really, I mean, I think we have made some real progress because of your leadership in designing the way this was augmented, and I very much appreciate it.

Senator DASCHLE. Thank you, Senator Pryor.

Senator PRYOR. Thank you.

Senator DASCHLE. I want to move on to other issues, but before we do, I am still not quite satisfied we are there in terms of maxi-

mizing our advantages in having you all with us this afternoon, to give us your guidance on defining that negligible risk standard.

I mean, I think we are so close, and yet we are not quite there, and I just want to nail that down to the extent that I can prior to moving on.

So—yes, Mr. Vroom?

Mr. VROOM. One perhaps most important fundamental about that computation is—and I think this is widely accepted in the scientific community and elsewhere—is that risk is a function of toxicity times exposure.

Now Mr. Meyerhoff referred to the analogy of lead and the progress that has been made in minimizing exposure. OK, how does the toxicity of lead and the exposure of lead through phasing out of lead-based or lead content in automobile fuel or lead-based paints that children inadvertently ingested—how does that compare with the risk times—the exposure times toxicity of very minuscule and many times nonexistent residues of active ingredient pesticides in our food?

We need to put those kinds of things in the broad perspective, and I think we also all agree that we need to have more uniformity in terms of the standard between raw and processed food, that those dual standards are very anachronistic.

They are putting an unfair disadvantage on our farmers and the food sector in particular, because our dependence in the American diet on fresh fruits and vegetables has grown substantially since 1958 when Congressman Delaney introduced this clause. We had a much greater dependence on processed food in our diets at that time. Now we have much greater availability of fresh fruits and vegetables, thanks in large part to widespread refrigeration abilities to preserve and bring those products right into our homes and into our kitchens than we had 35 years ago.

All of those are very important factors. But the real basics are: Risk equals toxicity times exposure. All those are important variables that we can work on, but we need a new standard from Congress, and we need it sooner rather than later for the benefit not only of agriculture, but a lot of other industries that are going to be troubled by the Delaney clause.

And I suspect that NRDC has plans to litigate the Delaney clause against other important exposure factors, and perhaps that is not widely known, but it is not just a pesticide issue.

Senator DASCHLE. So there is no disagreement with the formula: Risk equals toxicity times exposure?

Mr. MEYERHOFF. No, I think there is disagreement. I mean, our view and the view that is reflected by the Waxman legislation in the House is that the fundamental goal of any pesticide reform should be to prevent unnecessary exposure to categories of particularly hazardous chemicals, and those are the probable human carcinogens, the nerve toxins, reproductive toxins.

Senator DASCHLE. But why? That is not in conflict with what Mr. Vroom said, is it?

Mr. MEYERHOFF. Well, maybe it is not. If it is not, we have legislation language we would be glad to sit down and share with him after this hearing.

Senator DASCHLE. Dr. Landrigan?

Dr. LANDRIGAN. This distinction between risk assessment and risk management that Mr. Vroom mentioned was the subject of a 1983 report from the National Academy of Sciences. I was a member of the Oversight Board at the NAS that oversaw the production of that report, so I am quite familiar with it. In a nutshell, risk assessment is science. It involves doing studies on exposed people; it involves doing studies on exposed animals; and calculating how many excess cancers or how many excess birth defects or how many excess cases of neurologic disease are going to occur in a million people who are exposed to a chemical at a certain level. That is what risk assessment is, and it is something that we achieve through toxicity testing.

Risk management is what I pay you to do. It consists of the Congress sitting down and saying that as a matter of public policy, we are going to manage risk so that no more than one excess cancer occurs in 10 people or in 1000 people or in a million people.

That is not science at all. It is public policy. The two should not be confused.

I would argue that there is a good case to be made for writing into legislation the statement—and it is a policy statement, not a scientific statement—and it is not subject to change as science advances—that this Nation will not allow more than one excess case of cancer or more than one excess case of birth defects to arise per million people exposed to pesticide chemicals.

That is your call, not mine.

Senator DASCHLE. But setting the standard is really a function of both management and assessment, and, I mean——

Dr. LANDRIGAN. Well, it is based on the assessment. It is based on the scientific data. But when the Agency sets the standard, they have to adhere to whatever benchmark you and the Congress prescribe.

Senator DASCHLE. And that is your standard? Your recommendation for a standard is to prescribe it in terms of lives per million; is that it?

Dr. LANDRIGAN. One excess case per million, yes, which is the same number that Mr. Vroom seemed to accept a few minutes ago.

I think we differ, though, in our approach as saying: Do not write it into law. I am saying: "By all means, do write into law, so it does not get eroded in the future."

Senator DASCHLE. Carolyn?

Ms. BRICKEY. Yes. One thing that I think gets missed in discussing this issue is that in a discussion of benefits, it is important to point out that we are not talking about how many benefits a pesticide has when it comes onto the market. If EPA has evaluated the pesticide and has decided it is safe enough to be approved, the product goes on the market. If it is a good product and people want to use it, they will buy it. Those are economic benefits.

It is not, however, the same thing to say that once a pesticide has been looked at by EPA and EPA says that pesticide does not meet the safety standard, that we ought to create an exception for that product and keep it on the market indefinitely because it has, quote, "benefits" in the marketplace. That is a position that the groups that I work with find unacceptable. I do not think it serves the public health to do it that way.

Senator DASCHLE. Yes, Mr. Bender?

Mr. BENDER. Mr. Chairman, I have almost missed the moment with this comment. But given your continuing interest in finding a definition of negligible risk, I would like to partially move back to something.

Another one of the worries about negligible risk is that it is—whatever definition we come up with is inherently arbitrary. For some reason, it tends to converge and has historically on this one in a million number.

I think that one of the problems with that is that we probably have not yet found a way to subject that definition to democratic processes. That is, I am not sure that we have found a way to ask the American people whether they would prefer to be exposed to, let us say, a *1-in-a-million risk* or 1 in 500,000 or 1 in 2 million.

Senator DASCHLE. Yes, Mr. Eckel?

Mr. ECKEL. Well, Senator, I have remained silent on the issue, because I believe very firmly that these decisions as far as food safety are concerned have to be decisions based on good science and medical research. I am a farmer. I'm not a scientist nor a doctor.

Having said that, the construction of your question limits my comment because you did not bring the benefit question into it until Ms. Brickey did.

The American public could not make a decision on what risk is acceptable unless they looked at the benefit.

Each of us sitting around this table took a risk in coming here today. I flew. Then I rode in an automobile. I crossed the street. Those were very real risks that the scientists and mathematicians can compute, what risk I took with my life.

I weighed that against the benefits or nonbenefits of the 3 million or 4 million farmers in this country who belong to American Farm Bureau would have if we did not represent ourselves here today and had agriculture structured without the benefit of our input. I said: "I will accept the risk."

And so I do not know how we can construct any analysis that does not take into account the benefit versus the risk. It puzzles me that while in this area we have been assessing risk and benefit for over 30 years, and now we think we have to regress, in most other areas of Government today when I hear issues being debated, we are saying: Well, we have to analyze the risk against the benefit and the risk against the cost.

And I would urge you that as you wrestle with the academic question of the establishment of the risk, to recognize that we must absolutely include in the legislation the analysis of the benefit, and I am not just talking about production in agriculture; I am talking about the consuming public.

Senator DASCHLE. Well, there is a consensus among the group that modification of the Delaney clause is appropriate or at least acceptable.

There is also a consensus that negligible risk, rather than zero tolerance, ought to be the standard.

There is some degree of agreement, I think, on the way in which one defines how you establish negligible risk. But I do not think that there is a consensus in this room with regard to that at this point.

I wanted to try to do it outside the context of the bills themselves and see if we could arrive at that before we politicize the definitions by associating them with the bills. But I think we will be here until midnight just trying to do that, if I were to pursue this any further.

But I want to depart from this issue, unless somebody else has a profound closing comment they would like to share with us with regard to negligible risk and what guidance you would give us.

Let us be honest. I do not think we are there yet. I think one of the reasons that this committee is not as far along in the process is because we are still talking out there, rather than toward one another. Until we start grappling with some of these tough definitions and issues, I think we will be back here, as Senator Pryor said, years from now.

And so we need to seize the opportunity, and you need to give us as much of your wisdom and experience as you can in trying to deal with it as effectively as possible.

I think we have made marginal progress this afternoon. But frankly I would like to keep the record open, and I would like to continue to solicit your guidance in this regard.

But it is very important that we address this issue. We cannot put it in writing unless we understand it in concept and have a better appreciation of the ramifications of what it is we are writing. Obviously, judging from the significant degree of concern with the way that is written, that is a profound problem that has yet to be addressed effectively in this committee.

Mr. MEYERHOFF. Let me just add one point, I think, because I do not want to get into "the Emperor has no clothes" here.

I am not sure that there is agreement even at this table that so long as we could define something as negligible risk, we would have solved the underlying policy questions that are here.

I think that I would talk about perhaps unnecessary risk or unnecessary exposure, because what I am thinking of when I am saying those words is: How do you drive the technology in agriculture, which I think benefits the American farmer and the consumer, so that over the next decade, as we go into the 21st Century, fewer chemicals are used on the farm, which is to everyone's benefit, I think perhaps to the farmer most of all?

How we get to that point, we are still far apart, I think.

Ms. BRICKEY. Could I suggest, Mr. Chairman, just two quick things that I think are important for this committee to do that could help this debate?

The first thing is that this committee needs to do everything possible to assist, promote, cajole, push EPA to reexamine these older products and get the unsafe ones off the market.

How are we going to create the market for new technologies if we keep these old, unsafe technologies out there? There is no way.

Farmers are businessmen. They are stewards of the land, but they are businessmen. They run their farms that way—with practices that they think are profitable and make it work. If newer technologies come out and older chemicals go away, those technologies will be transmitted and adopted.

The second way this committee could help this process is to do everything possible to promote reduction strategies in the use of

pesticides. As I said in my statement, if we do not attack the use of chemical inputs directly, we will never really do anything in sustainable agriculture that will benefit the environment and public health.

Senator DASCHLE. Good suggestions. Yes, Mr. Eckel?

Mr. ECKEL. Mr. Chairman, I would encourage you and your committee—and I recognize it is the Research Committee—to do as much as you can to create an environment for our farmers that provides us the best research and technology possible in the production of our food and fiber and to create a system that is consistent and predictable as far as its regulatory functions and that is not arbitrary or centrally planned in its decisions as far as what to remove or what to keep, be it an old product or a new product.

One of the problems that we have today is not the reluctance of farmers to use the new technology; as I indicated, I am using that every day.

The problem is that companies are discouraged from investing. When you talk about arbitrarily taking products off the market, who is going to invest in the new one? And that is part of the problem that I see that we are creating today with this doubt.

There is one other thing that I want to emphasize to you as the Chairman of this committee, and that is that this agricultural system that we have is a highly productive unit, but I think unfortunately taken for granted and far more fragile than what one would assess.

The fragility comes from the uncertainty of the farmer producer as far as his future and as far as his liabilities. The considered legislation proposed by the administration in this area is not different than it is in areas of labor and the environment or the Clean Water Act, where we talk about civil suits and civil actions and the liability of the agricultural producer, which is creating an environment back home where we do not know whether to stay in the business or not.

In 1982, Penn State University recognized myself, my brother, and my father as master farmers. We run a successful, profitable farming operation. I am 47 years old and should be investing in the future.

I have a friend in that same situation, another master farmer. Five are selected from about six northeast States each year—a select, successful group. He has the same feelings.

One might ask why? And the answer is very simple. We have been willing to endure the uncertainty of weather and of markets. We are becoming unwilling to accept the uncertainty of Government regulation and the economic uncertainty of financial success in the future as everyone zeroes in on us as an improper steward or operator.

One last concern—we will check the record to see if it is accurate.

When the Alar scare was raised a few years ago, before I made a comment on it as President of the Pennsylvania Farm Bureau, I asked for a meeting with Dr. Charles Kroger from Penn State University's College of Food Science, not agriculture, to discuss the risks that were involved and implied with the Alar situation. I told

him: "Try to create it in layman's language that I, as a farmer, could understand." I also asked him to assess those risks.

He indicated to me that the risk from consuming that Alar-treated apple was the same as drinking water out of the public water supply. It was out of five times the same as breathing the air in this room.

He made one other comment that I cannot help but think, sitting at this table. He said: "94 percent of the carcinogenic risk from consuming food is naturally-occurring; 6 percent comes from pesticide use."

We sit here today and seem convinced that we will eliminate all of our concerns if we deal with the pesticide question.

I urge the committee to take a strong look at the direction we are going, the environment we create, and give strong consideration of weighing the benefits against the risk.

Senator DASCHLE. Let me move on to kids. I know that several wits made reference to children and the recognition that children are not adults and that we need to appreciate tolerance acceptability in a different context when it comes to children.

I was interested in the report, "*Pesticide in the Diet of Infants and Children.*" The quote that caught my attention was: "*To ensure compliance with good agricultural practices, tolerances are not based primarily on health considerations.*" That is a quote from "*Pesticide in the Diet of Infants and Children.*"

Dr. Vroom, in testimony—or Mr. Vroom, in testimony before the House, suggested precisely the opposite, that "pesticide tolerances are not set at particular levels in order to provide agricultural benefits," end quote.

So there seems to be some difference of opinion as to what it is that determines tolerance levels. Is it production or is it health, especially as it relates to children?

I would be interested in a discussion on that point.

Mr. Vroom, do you want to start? Are the two comments at odds with one another?

Mr. VROOM. The system by which our industry's products are regulated are required under the protocols developed by the EPA, published in the FEDERAL REGISTER and of longstanding existence. So the threshold that is established for the tolerance is computed off of a model based in laboratory analysis exposing laboratory animals at a "no-effect" level, but we are also required to test and expose animals at much higher doses than that.

And all of that data is weighed by EPA scientists. At the no-effect level, we are then forced by the Agency's approach and protocols to put a safety factor on top of the no-effect level, which gives you an additional margin of safety, below the no-effect level.

At this point the registrant (the manufacturer of the compound) has to figure out what crops to put on the label within the available exposure acceptance, known as the tolerance level.

So we believe fundamentally and firmly that tolerances are indeed based in a health assessment and knowledge that comes out of hundreds of millions of dollars of laboratory testing conducted under protocols published by EPA.

We also believe that Dr. Landrigan and his panel are correct in suggesting that improvements can be made. They are incremental

improvements, not improvements that would suggest that the sky is falling and that Chicken Little would predict that American agriculture is poisoning all of us.

But incremental improvements can be made, should be made, and the system can be changed. That flexibility exists in the current law for EPA to make those regulatory changes.

They have already made some changes in the process and new legislation is not required to force EPA to do that. I think there is adequate public pressure from the Academy, as well as the news media coverage of the Academy's report. Progress is being made.

Senator DASCHLE. Do you share that view, Dr. Landrigan?

Dr. LANDRIGAN. Well, not completely. Tolerance, of course, is like a speed limit; 55 miles an hour, at least in my State, is the tolerance for driving on the highways, 65 in some Western States.

The basic problem is that some of the tolerances for some chemicals are set at several hundred miles an hour or even 1000 miles an hour.

Under section 408, tolerances are established through a balancing process. Health considerations figure in, and toxicity test results figure in. But these factors are then weighed against economic considerations and considerations of agricultural practice. The unfortunate reality is that in that balancing process, the health concerns often lose out.

Let me talk in a little bit more detail about a document I mentioned earlier. Senator Kennedy asked Ms. Linda Fisher, who in the previous administration was the assistant administrator of EPA for Pesticides and Toxic Substances, to provide the Senate Agriculture Committee with a listing of pesticides for which the tolerance exceeded what is called the reference dose. The reference dose is also referred to as the "acceptable daily intake"; it is a number that is more or less health-based that tries to quantify the concentration of pesticide that can be safely allowed in a food.

There were a couple of pesticides at the top of this list for which the level tolerance exceeded the reference dose by a factor of more than 1000. There were 2 or 3 single-spaced pages of chemicals for which the tolerance exceeded the reference dose by a factor of more than 100. In short, there are a lot of chemicals where too much pesticide is allowed in food to be safe for children.

Now I accept what Mr. Eckel has been saying. The American food supply is, to be sure, the best in the world. I have worked in Third World countries. I have seen children with kwashiorkor dying of malnutrition. I have been in Nigeria; I have been in El Salvador; I have seen malnutrition there close up. Also I have seen malnourished kids in our inner cities in this country.

But these are two different issues. We are talking here about making the world's best food supply better. We are not comparing the United States with a Third World country.

And I really think that the power exists within our Nation's agricultural enterprise and within this Congress to accomplish just that.

Senator DASCHLE. Is it possible to set a single safety standard for kids and adults?

Dr. LANDRIGAN. Well, as a pediatrician I would proceed by identifying children as the most vulnerable members of our population

and then I would set the standard low enough so that the members of the most vulnerable group are protected. If the most vulnerable are protected, then everybody is protected and you achieve the goal of a single standard.

Senator DASCHLE. Mr. Vroom, I saw you shaking your head, that you thought it was. Is that the standard you would use?

Mr. VROOM. Not exactly, but I think—we are certainly in the same universe and on the same page and within the same book of answers.

Unfortunately my scientific advisors are not here, and so I am struggling to try to remember what I know about the reference dose number that is in the letter that Linda Fisher submitted to Congress that Dr. Landrigan is referring to.

It is a separate set of numbers that were devised primarily, as I recall, for an acute exposure measurement and were devised separately from carcinogenic effects considerations. I would like to be able to submit to you our perspective from a scientific standpoint about those comparisons of tolerance versus reference dose, and I am just not in a position to be able to give you any more information than that, because I do not have my experts with me.

But let me say again that I believe that Dr. Landrigan and our industry agree fundamentally on the fact that we can get there. I think that his statements today might lead one to believe that the sky is falling and that some kind of wholesale change is required, that perhaps Congress needs to jump in and force action.

It is our belief that EPA is carrying out, in an orderly fashion, the recommendations of the NAS report on infants and children and that incremental progress is underway and that no extraordinary pressure additionally from Congress or change in law is necessary, given what we are seeing in the way of progress.

And I would be interested to know whether you agree with the fact that the Agency is progressing, Dr. Landrigan?

Dr. LANDRIGAN. Well, the sky is not falling, nor does the National Academy report say that it is.

What we said is that the present pesticide tolerance-setting system needs to be improved. The Agency is making some progress. They could perhaps use some prodding from the Congress.

Mr. VROOM. They could certainly use more resources from the Congress.

Dr. LANDRIGAN. They could use more resources. We agree on that.

Senator DASCHLE. If there is no other comment on that issue, let me just——

Mr. MEYERHOFF. Let me say one thing on Alar, since it was brought it up.

Senator DASCHLE. Yes, Mr. Meyerhoff?

Mr. MEYERHOFF. Because I think it is a good—maybe it is a textbook case of why the existing system does need reform, and you can cry wolf, but you can also cry sheep. Every committee of this Congress that has looked at the pesticide law for the last 30 years—I can go back to the Moss Committee, you know, more than 20 years ago that found that the American pesticide laws—and this is a direct quote—"are an abysmal failure and in need of a complete overhaul."

I do not think we need to debate at much greater length that the existing system does not work, at least not work as well as it could. I do not think it benefits the American farmer, frankly, to have agriculture be the number one source of surface water pollution in the country, to have drinking water wells in California being closed down because of DBCP, to have problems in the Great Lakes where we are finding wildlife that are being deformed in all likelihood because of DDT and other chemicals.

I think that we do need to change things here. When it comes to infants and young children, I would first point out that the risk to infants and young children, as quantified by EPA from Alar, were greater than 1 in 10,000. Our assessment was 1 in 4000. You know, Mr. Vroom's number was 1 in a million.

And EPA recently reaffirmed, based upon the industry's own test data, that that chemical, using a cost-benefit standard, should be off the market. So I believe that the acted correctly on Alar, although 20 years too late, and an entire generation of children was exposed unnecessarily to a chemical that was a probable human carcinogen.

And I go back to lead. I think the model for infants and children should be the model we have used for lead. We would not say: Let us have a little bit of lead in infant formula. We would not say: Let us have a little bit of lead in gasoline, when we can remove it. If you can reduce or eliminate exposure to these compounds, whether it is lead or dioxin or the 73 pesticides EPA has now said cause cancer, the policy should be to find ways to reduce or eliminate that exposure.

Senator DASCHLE. Thank you, Mr. Meyerhoff.

I want to finish our hearing here this afternoon. But I would like to throw out one last issue that critics and advisors alike have given us a good deal to think about, and that has to do with enforcement powers and the time within which decisions are made. Obviously that has a profound effect as well on everybody at the table.

Is there a consensus about the need for enhanced enforcement in some circumstances and the need as well for expedited decisionmaking?

Ms. BRICKEY. I do not think there is any question that we need expedited decisionmaking. A chemical that triggers what EPA calls a "special review," which means there is a health problem here we have to deal with, can sit over there for 7, 10, 12 years before final action occurs. That is unacceptable.

The legal procedures that are involved in taking a chemical off the market once the Agency decides the chemical is unsafe are horrendous. There are all kinds of barriers to leap through to get that done.

The law is broken and needs an overhaul. This committee knows very well how difficult and tough these issues are. But the law is not working the way it was intended to work.

Senator DASCHLE. Does everybody share that point of view?

Mr. VROOM. No, Senator.

Senator DASCHLE. You do not.

Mr. VROOM. I agree that special review is what consumes great amounts of time in terms of analyzing a theoretical or a potential problem with regard to one of our compounds.

Special review does not exist within FIFRA. It is a policy that was manufactured by the Environmental Protection Agency and not prescribed by law passed by this Congress.

The law says that you take three steps in cancellation. One is consultation with USDA. Number two is that EPA consults with a science advisory panel. Number three, it goes to an administrative law adjudicatory hearing.

There have been three cancellations of products in recent years. In the provisions that are prescribed by FIFRA, those 3 steps, the average amount of time that those 3 steps have taken is 21 days for the cancellation hearings. The longest was 35 days. It is not several years.

What takes time, in terms of special review are in many cases EPA requiring tests to be redone because they lost the data that was submitted originally, or there is a change in the thought process at EPA with regard to the protocols under which a test was done. Sometimes these are 3-year animal studies. You cannot redo a 3-year animal study in 90 days.

So Congress ought to give some encouragement to the Agency to streamline the special review process and perhaps bring it further out into the open. But that which is prescribed in law on cancellation does not take that much time.

Mr. MEYERHOFF. We said support an amendment to FIFRA that would require that cancellation hearings be completed within 30 days.

Senator DASCHLE. Within 30 days?

Ms. DUGGAN. Absolutely.

Mr. MEYERHOFF. If 21 days is the model, I would fully support that.

Senator DASCHLE. Does anyone disagree with that?

Ms. DUGGAN. The food industry is very supportive of trying to streamline the cancellation process, and we have traditionally supported moving to a notice and comment type system instead of the adjudicatory hearing.

But these are really splitting hairs. I mean, what we want to do is get from something below 6 years to maybe 16 months, and we think that those kinds of provisions are in 1478 and in some of the other bills—this is actually a place where there is some conceptual agreement with the administration in the industry.

You also need to be able to give them the ability to decouple suspension from cancellation, so they can move forward on one without having to do both.

And from our point of view, that was one of the biggest issues in Alar, is that they could not decouple suspension from cancellation, and if they had had that ability, it would not have taken so long.

Ms. BRICKEY. The suspension provisions in the administration's bill and in your bill would not address the suspension issues that were part of the Alar controversy.

Ms. DUGGAN. Perhaps. But they still need to be done. But it still needs to be done. We think that will go a long way to improve the decisionmaking.

Senator DASCHLE. Well, this has been an extraordinarily productive session for me and I know for my colleagues. I really appreciate everyone's willingness to share their views with us and to present the testimony. We have got quite a diverse group, but I do believe that through that diversity comes education, and we have certainly been educated this afternoon.

The record will remain open for 5 days. If anyone wishes to make additional comment, they are welcome to do so.

Again, my thanks to all of you for being here.

[Whereupon, at 4:39 p.m., the subcommittee was adjourned.]

APPENDIX

PREPARED STATEMENTS

Carolyn Brickey

Mr. Chairman, and Members of the subcommittee, thank you for this opportunity to express the views of the National Campaign for Pesticide Policy Reform about the administration's proposal and the need for pesticide reform. I am executive director of the Campaign which is a clearinghouse for a coalition of 51 organizations. A list of the coalition is attached.[1] I think that an important first step before evaluating any pesticide proposal is to ask ourselves what is wrong with current law.

First, too many regulatory burdens fall on EPA. This is important not because we are saying "poor agency," but because there are insufficient resources to overcome the burdens. The consequences of this overburdening are real. Some examples of it include:

(1) There is a bias toward old chemicals that stay on the market. This results in a critical stumbling block to replacing bad technologies with newer, better ones. You cannot drive the development and adoption of a safer method (less pesticide reliant pest management systems) with "old tools" (conventional farming practices and heavy chemical applications).

(2) The Agency has a heavy legal burden to show that the risks of a pesticide do, or do not, exceed the so-called "benefits standard." As a result, EPA scientists tend to ask for another study when confronted with new information about the health risk of a pesticide. It takes a year or two to obtain and evaluate the new study that may result in yet another study, and so on. This is a kind of data deadlock that prevents the job from getting done, and is why a pesticide may sit in special review for 10 or 12 years.

(3) The cumbersome procedures of FIFRA add to the difficulties presented in A and B above. The resource drain and time involved, and adjudicatory loopholes available in suspending or cancelling a pesticide far exceed other health and safety statutes. It's a lawyer's paradise if he or she is representing a pesticide manufacturer, but it does not serve the public.

The result is that little gets done. The program becomes a paperwork treadmill. The objective becomes managing the paper not the risk. This is the primary function of the current program.

The solution is to place the burden on the registrant where data are inadequate. The responsibility to turn the "unknown" into the "known" should be on the registrant. For example, EPA is examining hundreds of older active pesticide ingredients in the reregistration program. If the registrant does not provide requested data within EPA's deadline, the product is suspended. This is a data forcing mechanism.

Second, "new science" is not taken into account. For all of the industry's talk about sound science and how outdated the Delaney clause is, there is little decision-making in the pesticide program to reflect the newer public health concerns about

[1] Retained in Committee files.

health effects beyond cancer. A grossly over valued risk assessment system prides itself on the use of "Q Stars" (risk factors) and other terminology that does not take multiple exposures into account, assumes that cancer is always the most sensitive endpoint that must be used to regulate pesticides, and does not adequately protect children and farmworkers from pesticide exposures.

The concept embedded in the Delaney clause of preventing exposures by keeping a harmful pesticide out of our food, water, and environment seems prudent to me. More to the point, however, new science is not about blasting Delaney. It is about pesticides and other chemicals that may cause irreversible damage to developing embryos leading to loss of function of the endocrine, immune, and nervous systems in exposed individuals. It takes only an extremely small quantity of these chemicals at a critical time during development to lead to these functional deficits. The effects are often not visible at birth and are more often expressed as the individual matures, leading to neurological and immune problems, and reproductive dysfunction, including reduced fertility. These effects that appear to be hormone-like, causing disruption of the endocrine system, are serious health effects that we are only beginning to understand how to test and detect, much less regulate.

Third, sound science tells us that the current tolerance-setting system isn't protecting children from unsafe pesticide exposures. A set of carefully considered recommendations from the National Academy of Sciences (NAS) must be thoroughly implemented to protect children. There should be no room for politics here. A little bit of discretion can be too much of a bad thing. The law must put the burden on the manufacturer to provide the data when the company wants to keep a pesticide on the market and EPA says the product is too risky for exposure to children. In the absence of data proving safety for children, the pesticide should be removed from the market. The only way to drive the production of data is to put the burden on the registrant.

Fourth, both FIFRA and FFDCA as currently constructed are overly discretionary. Is this an indictment of EPA? No. There are many well-intentioned, hard-working folks at EPA who try to do the right thing, but without a legal mandate, individual decisions become too politicized to make. The manufacturer complains, certain agribusiness interests complain, and the system becomes mired in red tape.

I must say that those farmers who actually use pesticides and complain about losing unsafe ones remind me of airline patrons who scream because they can't get flights in hurricane weather. Does one really want to fly in that weather? Sometimes members of Congress complain and threaten to intervene legally. Historically, OMB complained, USDA complained . . . the result was that resources were used to defend a decision that is designed to protect the public and subject it to undue delay, weakening, or even inaction. This is not about which party is in power; it is about the ability to act quickly and decisively to protect public health.

Every knowledgeable person in Congress can think of examples where this intervention in the process occurs. Does this mean that I think there should be no involvement by affected groups, inter-agency process, or that registrants shouldn't have their say? Of course not. But it does mean that once meaningful public participation is over and EPA has concluded that the pesticide has one or more unsafe health impacts, decisive and swift action should occur. That seldom happens.

Fifth, new action-forcing mechanisms are needed that require regulatory action once an administrative finding is made that a pesticide has one or more unsafe effects.

Changing the food safety law will not be effective if substantial and concurrent amendments are not made to FIFRA. FIFRA is too much about managing the use of pesticides instead of reducing the dependence of on chemical pesticides. The new law needs to implement a reduction in the overall use of pesticides where possible. Research and technology transfer must be connected to replace pesticides that are unsafe particularly where current alternatives are limited or are not readily available.

Sixth, we need to end the double standard which results in the annual export of at least 100 million pounds of pesticides too dangerous for our own use here. These include those which have been banned or never even get on the domestic market. One recent example is the insecticide mevinphos (Phosdrin) which was taken off the domestic market June 30 for causing farmworker poisonings in the United States but may continue to be made and exported for use by farmworkers overseas.

The double standard is both a moral and economic one—moral because current law implies that the lives of others overseas are less important than those of people in the United States and economic because farmers overseas will continue to be able to use pesticides like mevinphos which are illegal for use by our own farmers.

These are the yardsticks that I believe must be used to evaluate any new proposal. The Administration bill meets some of these tests, but not all. Recommended

FIFRA reforms represent an improvement over current law however, with important exceptions where provisions should be strengthened or deleted. FFDCA provisions that set timetables for revisiting tolerances that EPA finds will meet a new health standard are the most important reforms in either Administration bill. Other provisions take progressive steps to protect children from pesticide residues but do not go far enough to eliminate barriers to change.

EXPORT CONTROLS

Some needed changes in the way pesticide exports are regulated are proposed in the Administration bill. For example, a more aggressive United States leadership role is envisioned in this proposal than in previous administrations'. It would be illegal to export pesticides banned for human health effects as well as other pesticides if a country requested us to stop their export. However, unregistered exports are not treated stringently enough to ensure that citizens in other countries and food imported to the United States are not harmed by United States pesticide exports. Too many exceptions and loopholes exist in this plan. There are often health and safety reasons that block the approval of a product in the United States that may be approved in another country.

PHASE-OUT AND PHASE-DOWN AUTHORITY

This new authority is an improvement over current law. It is, however, an example of good intentions that must go further. It does not require or trigger a strong regulatory response to newly discovered information about serious health effects. The provisions of H.R 4091, the Waxman bill, better reflect an approach to require action by the administrator when pesticides are classified as "highly hazardous" health threats.

These triggers would be activated when pesticides cause serious reproductive harm, are probable carcinogens, endocrine disrupters, bioaccumulative, highly persistent, or are Toxicity Class 1 pesticides. The Waxman approach represents a reasonable action-forcing mechanism which would remove some of the worst pesticides from the market, and allow some additional time to develop alternatives for those pesticides truly without substitutes. S. 1478, the Lugar-Pryor bill, includes no new action-forcing mechanisms.

Providing for an orderly marketplace transition from 1950's technologies to practices that will take agriculture progressively into the 21st century is desperately needed. We are not helping farmers by encouraging the status quo—just like we wouldn't be doing a favor for the airline passenger who gets his or her wish to fly in a hurricane.

MINOR-USE PESTICIDES

First, the issue and then the concern. There is a real anxiety on the part of certain producers that will or are "losing" pesticides in the reregistration process. I continue to believe that there are three primary reasons for such losses by minor crop producers. The first is that a registrant decides that a certain pesticide will not meet newer health and safety requirements and so the registrant drops the reregistration effort.

The second is that a company has had a registration that is only marginally profitable because the "major" uses—wheat, corn, cotton, or rice—have been overtaken by newer products, and it is not worth the cost to perform core health and safety tests on the product.

The third situation exists when the registrant registers or reregisters a product for one or more "major" uses but is delayed or reluctant to pay several hundred thousand dollars for residue chemistry tests for one or more minor uses.

In neither of the first two cases is it feasible or reasonable to ask the taxpayer to foot the bill for these expensive tests. So what then is the minor use answer? There are two things that public and private sector research can agree to—developing and transferring newer nonchemical alternatives to farmers of minor crops and assisting them to access residue chemistry more quickly for safer, new pesticides in the short-term.

The answer cannot be to allow unsafe pesticides on the market longer just to satisfy the needs of producers for older, cheaper pesticides. Instead, gaining access to new products and technologies is the answer for farmers. Producers of minor crops should get on the front of the train, not ride on the caboose.

SECTION 18 AUTHORITY

While we recognize that farmers and public health officials can meet with unexpected emergencies for which the registered pest control tools available cannot do the job, the section 18 program continues to fail in its protection of public health and the environment. Since the adoption of regulations in 1986, which were intended to rein in the program, we have seen a significant increase in the issuance of permits across the board. This raises serious questions about the effectiveness of the program, not only in its response to pest problems, but as a means of promoting the adoption of practices that prevent future emergencies.

When evaluating EPA's emergency permits, we see that the problem of repeat emergency exemptions persists. EPA estimates that more than half of the section 18 exemptions granted during fiscal year 1988–91 were granted for at least two consecutive years.

Section 18 may be used to either promote or discourage the implementation of pesticide use reduction strategies. States and EPA should be required to showcase successful management systems that use a minimum of toxic chemicals, and these should be complete systems. If the law and its implementation addresses the system as a whole and requires States to undertake preventive action, then reduced use systems can be enhanced. The program must consider nonchemical controls, and prohibit consideration of the contribution of agricultural practices that constitute obvious mismanagement, which could be used to promote biological approaches to pest management. Beyond changing the basic thrust of the program to ensure that the section 18 program breaks the cycle of pesticide reliance on increasingly toxic materials, the program should: (i) notify all interested parties, including the public, of the opportunity to comment on all applications for exemptions; (ii) not allow the use of unregistered products or those with significant health and environmental testing data gaps; (iii) ensure enhanced Federal enforcement of use restrictions and other compliance questions; and (iv) require use records and improved oversight of State enforcement of the program.

PESTICIDE RECORDKEEPING

The significant difference the Campaign has with the administration's bill is that we need use reporting as well as recordkeeping. Reporting is clearly a victim of political rhetoric, because farmers already keep records for business and tax purposes. The largest States already require that such data be reported. These data can help inform us about the nature of pesticide use—how much and where. If pesticide use is to be regulated in a more specialized way to enhance ground water protection, for example, reporting of records is needed. Furthermore, if we want to require importers to provide more information, we need to require our own producers to meet similar recordkeeping requirements.

Most savvy farmers do not fear use reporting because they know that use records will show that they are running their businesses by the book. They are not afraid to report and share their records with the public. It is time that Washington, DC catches up with the real world on this issue.

CITIZEN SUITS

This is a good concept from which no farmers should be exempted. Why? Because its real purpose is to get State agencies to enforce the law. It is also a good incentive to get everyone to follow the law when all parties are on notice that a lax enforcement agency won't protect their illegal action. Finally, we have to remember that there are few field personnel and small budgets to enforce the law. We are almost dependent on the good will of producers. There is a lot of that but not enough to always protect the workers and neighbors of some farmers. In addition, provisions for citizen suits in other environmental laws, despite dire predictions to the contrary, have been implemented and the sun still rises in the morning.

A NEW HEALTH STANDARD IN THE FFDCA

Use of the "reasonable certainty of no harm" standard is an improvement over the standard in current law, section 408, which encompasses a version of risk-benefit analysis. However, a great deal of discretion is allowed in the proposed standard which is premised on the very imprecise concept of negligible risk. S. 1478, the Lugar-Pryor bill, allows even more discretion. Numbers are the name of the game in this arena, and they can move the risk up or down—mostly down—dramatically. Also, don't forget that to get this new discretionary standard, the Delaney clause would be deleted—a trade that is too expensive unless strong health-based mandates that expand tough protection for other health effects besides cancer are in-

cluded in the law. Further, delaying the health standard or phasing it in to replace—finally—economic benefits is not good policy. Economic benefits, as defined in current practice, are too narrow and parochial. Remember that we are talking about exceeding the new health standard in order to use these benefits. Only a true lack of alternatives or an averted health risk should ever be figured into the calculus of eliminating a pesticide based on its health risk.

TOLERANCE ASSESSMENT DEADLINES

This is the heart of the administration's bill. Damage it and the body stops working. Without these new requirements to force registrants to show that tolerances meet the new standard, reregistration will continue to rattle along at a stultifying pace—one that does not reflect risk reduction priorities.

Yet too many of the administration proposed provisions are based on evaluation of data "where it is available." These provisions do not drive data; they merely require its use where it exists. This is a major difficulty in the way in which the administration proposes to reassess pesticide residues to better protect children. The lack of provisions driving the development of new data and making it the responsibility of the registrant is a major failure of the Administration bill. Remember, this is one of the yardsticks I mentioned—burden shifting to the registrant and ending the data deadlock.

RISK REDUCTION VERSUS USE REDUCTION

While risk reduction is an important goal of EPA activities, it is limited in scope in several ways. First, the process of regulating one pesticide at a time is like tying your shoes together and trying to walk around the world. Could anything be slower? Second, the lack of cumulative risk evaluation means that often exposure to a number of different types of compounds is truly understated and ignored.

Third, one has to know or suspect that there is a specific problem in order to act on it under the risk reduction paradigm. Fourth, despite the presence of pesticides in ground and surface water nationwide, little is being done to eliminate pesticide leachers.

Despite the new devotion to the concept of Integrated Pest Management (IPM), pesticide use per acre is going up. Since 1966, the pounds per acre of active pesticide ingredients applied to United States cropland have increased 125 percent. In 1966, 1.2 pounds per acre of active ingredients were applied. By 1991, the amount had increased to 2.7 pounds per acre. One in 10 wells is contaminated with at least one pesticide, and more than 440,000 rural wells contain pesticides. Levels of Atrazine and Alachlor have exceeded Federal drinking water standards in the Mississippi river basin by 52 and 32 percent, according to USGS. On a one time/one hit basis, the levels are far higher: 1000 times the EPA standards for Atrazine, for example.

Reducing the use of pesticides in our environment is an important, cost-effective pesticide-related act of pollution prevention we as a society can take. Two recent reports document the wisdom of this approach—NAS' *Soil and Water Quality: An Agenda for Agriculture* and the Office of Technology Assessment's *Beneath the Bottom Line: Agricultural Approaches to Reduce Agrichemical Contamination of Groundwater.*

This approach is one that benefits farmers, their families, workers, and communities. When they adopt alternative approaches, farmers can save input costs and eliminate contamination risks to their own or their neighbors' wells, as well as surface water near their land. It is the right way to go. This is the way to take high quality, safe agriculture into the next century. Other countries have already begun programs to reduce use.

RESEARCH, EDUCATION, AND TECHNOLOGY TRANSFER

How can use be reduced without hurting farm viability? Farmers have been actively participating in on-farm demonstration and research projects for the last decade. Small grants provided directly to farmers through the USDA Sustainable Agriculture Research and Education Program (SARE), State funded Sustainable Agriculture Demonstration Programs and Foundation Grants have shown that profitable alternatives exist that significantly reduce pesticide use. These on-farm research projects coupled with field days and farmer led workshops have also demonstrated that farmers are more likely to implement sustainable practices after being "educated" by fellow farmers. The concept is "letting the best teach the rest." Using documented successes of farmers in a particular region growing specific crops, measurable use reduction goals can be implemented. The involvement of State agencies and the USDA extension service can help promote new strategies. USDA research needs to focus on experimentation and implementation of environmentally sound agricul-

tural practices. Programs such as SARE need to be expanded and fully funded and coupled with other USDA programs like the Water Quality Incentives Program (WQIP) and the Integrated Farm Management Program Option (IFMPO) which provide incentives and cost sharing for the implementation of proven, environmentally sound practices. Those actions need to occur now, not in 10 or 20 years.

Clearly, neither use reduction nor risk reduction alone is enough. Both must be implemented together to have the safest possible food and water supply and a cleaner environment.

NEW FIFRA CANCELLATION AND SUSPENSION, FFDCA PROCEDURES

These procedures would be vastly improved by the enactment of the Administration bills. However, there is still no new emergency authority for suspensions. The bill would not solve the dilemma presented by Alar—a pesticide presenting a chronic health risk to children that EPA repeatedly said should be removed from the market more expeditiously than in a regular cancellation. The ridiculous outcome in the Dinoseb case—where EPA was required to document the impact on every crop use of a pesticide that was causing serious reproductive hazards—would be overridden by this bill. S. 1478, the Lugar-Pryor bill does little to remedy this problem. A bill Senator Lugar introduced 3 years ago better addressed this problem.

COORDINATION BETWEEN FIFRA AND FFDCA

The administration's FIFRA bill makes it clear that if a pesticide tolerance is revoked or a petition is denied, the registration must be cancelled or amended to reflect this action. However, the administration's FFDCA bill does not include a provision to revoke a tolerance if a registration is cancelled. Why? Some kind of interim food chain pipeline can be provided for in addition to this needed corresponding change. Again, this should not be a discretionary matter. It takes time and resources to act affirmatively on this matter. Sometimes the action is far from expeditious.

NEW LABELING AUTHORITY

EPA badly needs new authority and control over product labeling. In certain circumstances the Agency has in the past not known the actual contents of an older product it is asked to register. Nor could it insure that the label actually met the requirements of the law.

Albert H. Meyerhoff and Jennifer Curtis

INTRODUCTION

I am Albert H. Meyerhoff, senior attorney with the Natural Resources Defense Council (NRDC), a national nonprofit environmental organization dedicated to protecting the public health and the environment with over 170,000 members. For more than two decades, NRDC has been actively involved in the host of issues presented by the increasing use of pesticides and their impact on the environment. I appreciate this opportunity to testify today regarding legislation proposed by the Clinton administration to amend Federal pesticide laws. Before addressing the Administration bill, however, I would like to briefly summarize the administration plans to obey the law as written.

THE DELANEY CLAUSE: A CLEAR AND PRESENT MANDATE

As one of her first acts following confirmation as EPA Administrator on February 2, 1993 Carol Browner indicated that one of her top priorities was to achieve comprehensive reform of the Nation's antiquated food safety laws. However, as a condition of that reform, which included replacement of the Delaney clause, she indicated that the pesticide laws should be amended only if to do so would "give the public more protection, not less." (*New York Times,* February 1, 1993 at p. 1.[2])

Absent legislation, and unlike its predecessor, this administration has repeatedly emphasized its commitment to comply with and fully implement existing law, including the Delaney clause. Thus, at a September joint hearing of the Senate Labor and Human Resources Committee and the House Energy and Commerce Committee, Subcommittee on Health and the Environment, Administrator Browner stated EPA's intent to comply with the precedent established in *Les* v. *Reilly* and imple-

[2] Retained in Committees.

ment Delaney in a timely fashion. (Hearing on Legislation to Amend the Food, Drug and Cosmetic Act, Washington DC, September 21, 1993.)

At an October 1993 House Government Operations Subcommittee hearing, Dr. Goldman spelled out the Agency's intention in more detail:

> [EPA will] immediately discontinue processing applications for experimental use permits, product registrations, and petitions for tolerances for chemicals that are potentially affected by the Delaney clause. It makes little sense to expend Agency resources to process applications for the same sorts of uses which we are in the process of revoking . . . [T]he clear legal interpretation of the U.S. Ninth Circuit Court's decision plainly applies to a number of other chemicals and their tolerances. Although there are a number of legal and policy issues which EPA has not yet settled, I have decided that we can quickly begin to make the policy choices and initiate actions on a number of existing tolerances. Accordingly, I expect that additional notices to revoke section 409 tolerances will be proposed within a matter of months. (House Environment, Energy and Natural Resources Subcommittee, Government Operations Committee, October 29, 1993.)

In response to questions from Subcommittee Chairman Synar, Dr. Goldman then provided a list of carcinogens potentially subject to Delaney, indicating that under EPA's plan for these chemicals, the Agency "will establish priorities and schedules over the next year for revoking food additive regulations and raw food tolerances, as well as possibly canceling registrations."

Responding elsewhere to industry criticism of EPA's intention to act on §408 as well as §409 tolerances in order to fully ensure compliance with the Delaney clause, the Assistant Administrator has also stated that:

> The EPA disagrees that it is mistaken to invoke the Delaney clause for raw tolerances under all circumstances. We are aware that, in many cases, the farmer does not know ahead of time whether a given crop is destined for the raw or processed market. It would be misleading and disruptive for the EPA to grant raw tolerances in circumstances where later the crop is destined for the processed market and, therefore, would have violative residues. (*Pesticide and Toxic Chemical News*, November 10, 1993, at 20.)

This administration's express commitment to Delaney implementation is refreshing since, in the past, at least for pesticides, the Delaney clause has been honored in the breach. The Agency's consistent approach throughout the 1980's with respect to carcinogens in food was to ignore or evade that historic statute. This approach is no longer legally permissible. The United States Court of Appeals has held, in *Les* v. *Reilly*, that pesticides present in processed foods, either due to concentration during processing or postharvest application, are subject to Delaney. The Agency's purported *de minimis* policy, allowing carcinogens based on the purported level of cancer risk, was rejected because "the language of the Delaney clause, its history and purpose, all reflect that Congress intended the EPA to prohibit all additives that are carcinogens, regardless of the degree of risk involved." (*Les* v. *Reilly*)

Moreover, under the Agency's well-established policy, and because EPA is unable to determine which raw commodities will or will not be processed, the presence of carcinogenic pesticides in raw commodities that are subject to processing is foreclosed as well.

Beginning to fulfill this commitment to Delaney compliance, EPA has now issued an updated list of those carcinogenic pesticides that have been identified as subject to the Delaney clause (copy attached). This is an important first step. However, in order to obey the law and protect the public health, it is now incumbent upon the Agency to take all appropriate steps, in a timely fashion, to revoke those offending tolerances. It has been 18 months since this administration first announced its intention to obey the law. It is now time to start actually doing so.

THE PROMISE OF THE DELANEY CLAUSE REMAINS UNFULFILLED

The essential premise of the Delaney clause of the Food, Drug and Cosmetic Act is as simple as it is powerful: what we understand best about carcinogens is the limited extent of our knowledge. (*See* "No More Pesticides for Dinner," *New York Times,* March 9, 1993, copy attached.[3]) Accordingly, the famous clause is grounded in a policy of prevention: prohibiting the addition of carcinogens in the food supply to prevent avoidable cancers in humans. This approach was deemed necessary by Congress, since the entire Nation's population would otherwise be

[3] Retained in Committee files.

routinely exposed to carcinogens in their daily diet. That premise remains as valid today as it was in 1958.

Accordingly, the philosophy behind the Delaney clause—preventing unnecessary exposure to hazardous substances—should be preserved—either by implementation of the existing law or in any new legislation. Prevention *is* worth a pound of cure. We *still* do not know whether humans are more or less sensitive than laboratory animals to carcinogens and whether one carcinogen may increase the cancer-causing effects of another. We *still* do not know the cumulative impact of dozens of carcinogens permitted in the food supply and the environment. Our existing tolerance-setting system is entirely predicated on a chemical-by-chemical, crop-by-crop, risk-by-risk approach, grounded in myopia, "managing" cancer, rather than preventing it.

The reality of life is that we are exposed to a multiplicity of toxic substances. Calculating the combined risks of these exposures is problematic at best; some 300 pesticide active ingredients are used on food as well as an imperfectly examined large number of "inert" ingredients. For the most part, existing EPA pesticide tolerances for allowable pesticide residue levels do not even attempt to calculate the aggregate human health risks presented, nor do they address the cumulative and synergistic effects on multiple pathways of exposure.

This is the fundamental flaw in the Nation's pesticide laws. And it is the fundamental flaw in the administration's proposal which, while improving the current system, keeps its essential "management" approach intact. We, instead, should follow Rachel Carson's advice of three decades ago:

> The ultimate answer is to use less toxic chemicals. This system of deliberately poisoning our food and then policing the result is too reminiscent of Lewis Carroll's *White Knight* who thought of a plan to dye one's whiskers green and always use so large a fan that they could not be seen.

THE NEED FOR PHASE-OUT

Since the time the Delaney clause was enacted:

- Conventional pesticide use in the United States has increased dramatically, from 511 million to more than one billion pounds. Total pesticide use, including wood preservatives, disinfectants and sulfur now exceeds two billion pounds annually, eight pounds for every man, woman and child in the United States.
- EPA estimates that one out of every 10 public drinking water wells in the United States contains at least one pesticide; their data indicate that nearly 10,000 community drinking water wells and over 440,000 domestic water wells contain pesticides. Seventy-four different pesticides have been found in groundwater which supplies drinking water for 32 States. Agriculture is also now the No. 1 source of pollution of surface water; pesticides have found their way into countless lakes, rivers, and waterways throughout the Nation.
- According to the FDA, at least 38 percent of the food supply contains pesticide residues. This understates the actual amount because routine lab tests detect fewer than half of the pesticides applied to food. Many foods sampled by FDA had more than one pesticide residue; some had as many as twelve.
- The bugs are winning. At the time the Delaney clause was enacted, 137 species of insects and mites had become resistant to chemical pesticides. Today, the number of resistant pests is almost 500 (as well as 100 species of plant pathogens and 48 species of weeds).

In 1972, Congress required that the chemical industry test their products and the Government reassess their safety. For 15 years, this requirement went largely ignored. Finally, in 1988, Congress established explicit timetables by which such testing must be completed, to be concluded by 1997, and for pesticides to be "reregistered" based on the results. Yet, to date, only 27 of 600 active ingredients have been reregistered (and EPA may miss this deadline by a decade or more). Nonetheless, in laboratory tests, *71* different pesticides allowed in food and the environment have now been found to cause cancer.

Mounting evidence suggests a strong correlation between pesticide exposure and the development of cancer in humans. A National Cancer Institute (NCI) study found that farmers exposed to herbicides had a six times greater risk than nonfarmers of contracting one type of cancer. Another study found a link between breast cancer in women and elevated levels of DDE, a metabolite of the pesticide DDT, in their fat tissue. Research also indicates that children in homes where household and garden pesticides are used are seven times as likely to develop childhood leukemia. There are still unexplained clusters of cancer among farmworker children at places such as McFarland and Earlimart, CA.

Those of us born after World War II—the "boomers"—have been accurately called "the children of the chemical age." It always seemed something of a compliment. But in a disturbing new study, researchers have found that "baby boomers" born between 1948 and 1957 are far more likely to contract cancer than members of their grandparents' generation. These scientists found persistent increases in cancer that could not be accounted for by smoking, aging, or better diagnostic tests. The types of tumors found to be increasing in the general population were also strikingly similar to those found in earlier studies of farmers who were exposed to a variety of carcinogens, such as fertilizers, pesticides, and other solvents.

Authored by epidemiologist Devra Lee Davis, the study, published recently in the *Journal of the American Medical Association,* found that cancers unrelated to smoking—that affect parts of the body other than the lungs, throat, and mouth—were occurring in white male "boomers" at triple the rate of their grandfathers. White women in the same age group had 30 percent more nonsmoking related cancer than their grandmothers. (*The study was conducted only of whites to avoid statistical problems having to do with diet.*)

Given this record, the case is compelling to, once and for all, end business as usual. American agriculture must move in a new direction—a direction that simply relies far less on toxic chemicals to produce our food. The first step in that journey must be the slow, but eventual, phase-out of "worst actor" pesticides, chemicals whose hazards have been well-known for up to 50 years. *See White Paper: The Need for a Phase-Out of Carcinogenic Pesticides,* Natural Resources Defense Council (copy attached).[4]

Thus, while many approaches to do so are feasible, the linchpin of any comprehensive reform legislation must be the accomplishment of the following three goals:

- Comprehensively deal with chronic health hazards from pesticides by phasing out those toxic substances identified as presenting known hazard to human health and the environment;
- Respond to the special risks pesticides pose to children as most recently recognized in the National Academy of Sciences report on that subject; and
- Substantially reduce overall pesticide use in American agriculture.

Absent such reforms, the Delaney clause should be left intact and its terms complied with to the full extent of the law. Consider the following:

PESTICIDE REDUCTION: THE POLLUTION PREVENTION SOLUTION

Current regulatory programs have been unable to reduce the hazards caused by pesticides. Ultimately, the most effective method for protecting public health and the environment is to reduce the use of pesticides at their source. Numerous reports document the potential and importance of reducing overall use of pesticides.[5] According the National Academy of Science's *Soil and Water Quality: An Agenda for Agriculture* NAS report,

> Source control to reduce the total mass of pesticides applied to cropping systems should be the fundamental approach to reducing pesticide losses from farming systems.[6]

Several European countries including Sweden, Denmark and the Netherlands have adopted national programs that incorporate the fundamental approach of pesticide use reduction. Concern about environmental pollution has prompted these countries to initiate programs aimed at reducing the use and emissions of, and dependence on, pesticides while maintaining viable levels of crop protection without decreasing crop yields.

Although not perfect, these programs are models for what is possible in the United States. The Swedish program achieved a 50 percent reduction in the weight of active ingredient applied between 1986 and 1991 and an additional 50 percent cut is currently being implemented. The Danish program achieved a 25 percent reduction between 1986 and 1990.[7]

Numerous methods are available to reduce agriculture's use of and reliance on pesticides. The National Academy of Sciences in their report, *Alternative Agriculture*

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[4] Retained in Committee files.

[5] National Research Council, *Soil and Water Quality: An Agenda for Agriculture,* Washington, DC, 1993.
Office of Technology Assessment, *Beneath the Bottom Line: Agricultural Approaches to Reduce Agrichemical Contamination of Groundwater,* Washington, DC, 1991.

[6] Soil and Water Quality, p. 82.

[7] World Wildlife Federation, *Pesticide Reduction Programmes in Denmark, The Netherlands, and Sweden,* November 1992, pp. 29–34.

documented the potential for reducing pesticide use through the adoption of integrated pest management and other practices and systems for agricultural sustainability. Such practices can lower costs for farmers and pest managers and in many cases increase the quality, productivity and yields.[8]

According to a 1991 NRDC report, *Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use,* techniques are available to reduce the use of pesticides between 25 and 80 percent on nine different cropping systems throughout the United States.[9] Depending on the crop, methods such as integrated pest management and biological, cultural, mechanical and physical controls can be implemented without significantly effecting crop yields or production costs (Executive Summary attached).[10]

Federal programs have failed to encourage and, in many cases, have impeded the adoption of pest management methods that reduce the use of pesticides. Farmers are interested in implementing new approaches but poorly funded and uncoordinated Federal programs have been of little assistance.

The public is looking to Congress for action. A comprehensive Federal program that encourages the trend toward reduced use of pesticides is long overdue. Legislation is needed to mandate a program that includes, at a minimum, the following major components:

(1) Measurable and enforceable pesticide reduction goals.

(2) Regional, ecosystem-based and crop-specific pesticide reduction programs that broadly involve farmers and other experts in integrated pest management and sustainable agricultural systems.

(3) Substantial resources directed toward technology transfer for pesticide reduction, including model demonstration farms and cost-share assistance.

(4) Prioritization of existing pest management research and extension activities toward development of integrated pest management and sustainable agricultural systems.

(5) Complete pesticide recordkeeping and use reporting.

(6) Establishment of pesticide reduction goals and programs for all Federal agencies.

(7) Creation of market incentives for farmers including through government procurement of certified-organically grown food.

(8) Development of nationwide initiative to reduce the use of nonagricultural pesticides.

ENVIRONMENTAL ESTROGENS: A WAKE UP CALL

For the reason why pesticide reform is critical, one need look no further than the Great Lakes, the source of 20 percent of the Earth's fresh water. Due to pollution from DDT (banned in the 1970's but still "out there") and other "environmental estrogens," male wildlife are literally being "feminized," born hermaphroditic with reproductive parts of both sexes or even female entirely. Waterfowl, turtles and fish also are suffering infertility, gross birth defects, and behavior abnormalities. Elsewhere, in the Florida Everglades, alligator eggs are failing to hatch. Male alligators are being born with extremely small phalluses, one quarter the normal size, and testosterone levels so low they are probably sterile. Florida panthers exposed to estrogenic pesticides have likewise experienced such reproductive failure; females are infertile, males sterile with low sperm counts. The "why" is no mystery.

Numerous pesticides and other compounds, like dioxin, lead, chlorine and mercury, have been found to mimic the female hormone estrogen, wrecking havoc on these animals' reproductive ability. Structurally similar to real estrogen, these compounds fit into estrogen "receptors" in the body, adversely affecting the endocrine system, disrupting normal sexual development. The most serious reproductive threat of these toxic substances is not to adults but to the developing fetus, by crossing the placenta during prenatal development. Levels of environmental exposure causing such effects are surprisingly low, equivalent to those also found in our own food and water. In other words, what we are doing to the wildlife, we may be doing to ourselves.

Consider the following:

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[8] Alternative Agriculture.

[9] Curtis, Jennifer, et al., *Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use,* Natural Resources Defense Council, May 1991, p. iii.

[10] Retained in Committee files.

- A Danish study of 21 industrialized countries documented a 50 percent drop in sperm count worldwide between 1938 and 1991. At the same time, the number of testicular cancers has tripled.
- In Taiwan, 118 boys born to mothers exposed to PCB's in their diet suffered reproductive defects including abnormally small penises—the same effect previously found in both wildlife and laboratory animals.
- Breast cancer will now strike 1 in 9 women. A Mount Sinai School of Medicine study showed that women with higher levels of the environmental estrogen DDE (a breakdown product of DDT) in their breast tissue were more likely than others to get breast cancer. Other studies are to the contrary.

Virtually all of us have measurable quantities of DDE, PCBs and other environmental estrogens in our bodies. "It's very possible and it's frightening that we might be drowning in a sea of estrogens" said Stanford endocrinologist David Feldman. Is the evidence conclusive? No. But multiple exposure to literally hundreds of different chemicals that can turn male animals into females, reduce sperm count, and cause infertility must be taken seriously. By what right do we risk the reproductive ability of future generations?

In late July 1991, a multi-disciplinary group of some of the Nation's leading scientists met in Wingspread, Wisconsin to discuss "*Chemically Induced Alterations in Sexual Development: The Wildlife/Human Connection.*" They concluded they were "certain of the following: a large number of man-made chemicals . . . have the potential to disrupt the endocrine system of animals, including humans. These impacts include . . . decreased fertility, decreased hatching success, gross birth deformities, feminization, and compromised immune systems. The effects are most often manifested in offspring, not in the exposed parent. [H]umans may be at risk to the same environmental hazards as wildlife."

THE ADMINISTRATION'S PROPOSAL: ONLY A STARTING POINT

In *Earth in the Balance,* Vice President Al Gore wrote this about agrichemicals:

> Over the past 50 years, herbicides, pesticides, fungicides and thousands of other compounds have come streaming out of the laboratories and chemical plants faster than we can possibly keep track of them. All of them are supposed to improve our lives . . . But too many have left a legacy of poison that we will be coming to terms with for many generations.

The Vice President had it right. Last fall, the Clinton administration admirably chose to break the logjam over pesticides. But, unfortunately, their initial proposal, reflecting an interagency compromise on agricultural interests and public health, missed the mark. At best, it is a first step. The proposal is opposed by every major environmental, consumer and labor organization in the country. Here's why.

Under current law, residues of dozens of cancer-causing pesticides are routinely allowed in raw foods, such as fruits and vegetables, through application of a notoriously weak, "cost-benefit" standard. On the other hand, as a result of a recent court decision, pesticides in processed foods are subject to the Nation's most health-protective statute, the Delaney clause, prohibiting *any* residue of a known carcinogen. The Clinton proposal would replace this admittedly schizophrenic scheme with a "negligible risk" standard to apply to all foods—raw and processed.

As always, the devil is in the details. First, the administration proposal does not specify precisely what constitutes such a negligible cancer risk—or even agree to include a definition in the statute itself. Instead, identifying the "acceptable" number of cancers permitted from daily exposure to pesticides in the Nation's food supply would be left to the discretion of both this and future administrations. Given typical industry influence over government regulators and the open hostility of *prior* administrations to pesticide regulation, this proposal offers little comfort.

Moreover, for at least the next decade, the administration's new standard will apply *only* when it will not result in "disruption of agricultural production." This loophole is left vague and undefined. But historically, for 30 years or more, virtually each time EPA has attempted to regulate a pesticide—from DDT to DBCP to EDB to Alar—efforts were stymied by overstated industry claims of just such predicted "disruptions."

The administration's proposal also responds only with vague generalities to a recent National Academy of Sciences study concluding that existing pesticide laws do not adequately protect infants and children from their daily dose of these poisons. And it does not adequately address the *cumulative* impact of exposure to the multiple pesticides found in our foods, including the ability of one toxin to greatly increase the hazard of another, called synergism. Rather than simply assigning individual "acceptable" residue levels, on a chemical-by-chemical basis, for the 300+ pes-

ticides used in food, any reform proposal should, instead, gradually eliminate the use of pesticides already known to pose the gravest threat to human health.

In addition, the administration's proposal falls short of developing a nationwide program to reduce the use of and reliance on pesticides. While an important first step, the administration's proposal is limited to authorizing establishment of reduced use pilot projects. Both farmers and the public deserve a comprehensive Federal program that establishes measurable goals for pesticide reduction, provides substantial resources for technology transfer and cost-share assistance for farmers and requires Federal agencies to take the lead in pesticide reduction efforts.

Conclusion

Years ago, a House committee found American pesticide laws "to be an abysmal failure in need of a complete overhaul." That conclusion remains accurate. Opinion polls conducted for the Food Marketing Institute and others confirm that public concern over pesticides is at an all-time high. Serious Congressional reform is required but will be accomplished only through leadership from the White House. Fortunately, time remains for the Clinton administration to fulfill its campaign promise to achieve tough and meaningful environmental protection, including long over-due pesticide reform. Otherwise, an historic opportunity—as well as the critical goal of reducing human exposure to these most toxic of chemicals—may be lost.

Jay J. Vroom

Mr. Chairman, and Members of the subcommittee, on behalf of the member companies of the National Agricultural Chemicals Association (NACA), I would like to thank the subcommittee for the opportunity to comment on S. 2084 (the "Pesticide Reform Act of 1994"), S. 2050 (the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1994"), and S. 1478 (the "Food Quality Protection Act of 1994"). As you know, NACA is the not-for-profit trade organization of United States manufacturers, formulators and distributors of agricultural crop protection and pest control products. Our membership is composed of those companies which produce, distribute and sell virtually all of the active compounds used in crop protection chemicals registered for use in the United States. Clearly, NACA's members have a vital interest in continuing to improve the processes which govern the testing, review, and approval of their products. These comments discuss the improvements to the present system which are truly needed, the consequences of not making those improvements, and how the specific proposals in S. 2084 and S. 2050 will, or will not, result in overall improvement.

THE NEED FOR LEGISLATION

The current legislative debate exists because the science which supports pesticide regulation has continued to evolve, while the laws and regulations governing pesticides largely have not. At the root of this debate is the 1958 "Delaney" clause, an anachronism which not only renders the FFDCA internally inconsistent, but also conflicts with FIFRA, the primary statute under which pesticides are regulated. NACA believes that there are two ways to resolve this inconsistency: Congress can modernize the FFDCA by eliminating the Delaney clause (replacing it with a single negligible risk standard for raw and processed food as recommended by the NAS in their 1987 report "The Delaney clause"), or EPA can modernize its policies which implement the Delaney clause (including a affirmative ruling on "the NFPA" petition). Either option will largely avoid the disruption to America agriculture which some have predicted if action is not taken.

This is not to say that other aspects of our pesticide laws could not benefit from improvement. To the contrary, through the ongoing legislative debate several areas of general agreement have emerged among EPA, the regulated community, and environmental activists.

Areas of agreement include:

- Delaney's "zero-risk" standard is no longer scientifically justified, is virtually impossible to achieve, and should be replaced with a negligible risk standard.
- A single standard must be set for raw and processed food. Current law treats them differently, and this makes neither scientific nor regulatory sense.
- Newer products, developed using state-of-the-art research and understanding, must be brought more quickly to the market. NACA has worked closely and effectively with EPA to improve certainty in efficiency in data requirements, and this process must continue.

- The administrative process for removing problem pesticides from the market takes too long. We need a new process that can allow EPA to take action quicker, while preserving essential due process rights.
- Re-registration is taking too long. The burden on EPA of reviewing mountains of data is staggering, but the task is essential to public safety and confidence. All parties have agreed that delays in this process serve no one, and real improvement must be found.
- Adverse effects from the loss of minor use pesticides are real, and growing. As this subcommittee well understands, this issue must be addressed.
- The process for making routine improvements in pesticide usage, such as *minor* label changes, could be improved.

While these issues are important, the single issue which brings us together year after year is repeal of the Delaney clause. If Congress cannot resolve that issue this year, the job of implementing Delaney in the wake of the *Les* v. *Reilly* decision will fall squarely upon EPA. As explained below, EPA has shown little willingness to reconsider old policies, or to incorporate modern scientific principles into its Delaney-implementation plans.

EPA APPEARS PREPARED TO PRESIDE OVER A REGULATORY "TRAIN WRECK"

One apparent consequence of the *Les* v. *Reilly* decision on Delaney policy is the review, and possible revocation, of a number of valuable food use tolerances. Because EPA may no longer utilize a *de minimis* exception to the Delaney clause when making tolerance decisions under the FFDCA, tolerances previously grated under that exception must be reviewed to determine whether they violate a strict reading of Delaney. However, rather than determining whether their pre*Les* policies are still justified (or legal), and rather than focusing on the ramifications of not reviewing those policies, EPA has instead concentrated its efforts entirely on obtaining a "legislative solution." This blind focus on legislation unnecessarily places the entire burden of reform on Congress. EPA should reevaluate what it can do to practically, and legally, implement existing law. Without such a reevaluation, EPA will create confusion, lose additional public confidence, and cause significant unnecessary disruption to agriculture.

For instance, EPA has consistently interpreted the *Les* decision in the most expansive manner possible, claiming that the decision itself actually requires specific regulatory actions, including the revocation of tolerances and cancellation of registrations. While denying that existing tolerances are a public health concern, EPA has warned that without sweeping legislative reform it will be forced to revoke dozens of needed tolerances, causing widespread disruption of agriculture, food processing, and pesticide industries.

Yet EPA continues to overlook the plain language of other sections of the FFDCA which would decrease the adverse effect of the *Les* decision on agriculture and the America public. EPA also has failed to implement policy changes which would reconcile agency practice with current law, and allow the Agency to focus scarce resources on areas of true concern. Many now believe that EPA has deliberately chosen to ignore these statutes and policies in order to create pressure for their many legislative recommendations. This tactic will also allow EPA to avoid responsibility when it begins to revoke large numbers of tolerances, and agricultural markets are disrupted.

EPA claims it has two options: massive tolerance revocation, or their legislative recommendations. In fact, there are at least six nonlegislative strategies to avoid significant disruption, all consistent with current law:

Grant the "NFPA Petition." In the fall of 1992, the National Food Processors Association (NFPA) and others filed an administrative petition asking EPA to (1) abandon its concentration and coordination policies (because they are illegal, and amount to improperly promulgated regulations), and (2) recognize the "flow through" provision of FFDCA §402. The petition was not published for comment until February 1993. Although a response is not required by a specific date, nearly 2 years have now passed without EPA action. Ignoring comments on the petition filed by hundreds of affected parties, assistant administrator Goldman glossed over the importance of the petition in testimony before Congress on October 29, 1993, stating that EPA was "reluctant to break new ground administratively" with the "interpretations" suggested by NFPA. This statement reflects a dangerous and unlawful unwillingness to consider proposals on nonlegislative solutions to the predicament caused by the Delaney clause.

Rescind its Policy of Intentional Inaction. On April 6 of this year, EPA announced via FEDERAL REGISTER notice that it had ceased review and processing of tolerance

petitions, as well as the associated FIFRA registration applications, if any of the uses "appear" to result in a residue that needs a food additive regulation which Delaney would bar. Without actually making a fact-based finding, EPA has arbitrarily blacklisted products and completely disregarded the rights of registrants and the needs of growers. Of course, the primary importance of this policy will be to slow, if not stop outright, the introduction of several newer and possibly safer pesticides. In so doing, EPA has illegally read the Delaney standard into both FIFRA and section 408 of the FFDCA, and denied registrants the opportunity to adequately defend their products before either the public or EPA.

Reconsider Outdated Policies. Many of the policies EPA has adopted in order to implement FIFRA and FFDCA mandates include unrealistic, conservative assumptions and unnecessarily stringent definitions. In some cases, the policies lead to contradictory results. For instance, many section 409 tolerances are required for foods which are not commonly understood to be "processed." While EPA has proposed redesignating dried hops as a raw food, it did so only after being required by Congress to do so in a appropriations bill. To date, EPA has failed to take similar action for dried raisins and figs. Additionally, current EPA policy requires section 409 tolerances for many food byproducts, even if they represent only a small portion of the food in a animal's diet. Although the law requires a tolerance only if the byproduct "is a substantial source of nutrients in the diet of the animal," EPA requires a tolerance for all such byproducts, even though many are no longer used in animal feeds (*e.g.*, dried apple and grape pomace, and dried citrus pulp), or constitute only a insignificant part of the animal's diet.

Other areas EPA has failed to address include (1) the "ready to eat" language of FFDCA, which, if given effect, would lead to more realistic exposure and risk (and therefore tolerance) assumptions, and (2) EPA's continuing focus on the theoretical possibility of concentration rather than on actual data or residues. Challenges to all of these outdated policies have been pending before EPA—unanswered—since at least September of 1992.

Recognize Advances in the Understanding of Cancer. EPA's reliance on overly simplistic category-based definitions of carcinogenicity fails to consider advances in scientific understanding, unique properties of various compounds, and mechanisms of action that may differ from one compound or test subject to another. Use of Maximum Tolerated Dose ("MTD") testing in regular protocol, and routine reliance on exaggerated exposure assumptions leads to results which have no real world significance, and are irrelevant to a determination of whether a compound "induces cancer . . . in man . . . by tests which are appropriate for the evaluations of the safety of food additives," and contribute to loss of consumer confidence in food safety. Other countries with modern scientific and regulatory systems no longer rely solely on MTD.

Grant Hearings to Registrants Whose Compounds are Suspected of Violating the Delaney clause. A announced last year the proposed revocation of the seven tolerances involved in the *Les* decision without first giving the registrants an opportunity to present evidence on whether those residues did in fact concentrate above the level of the raw product tolerance, or whether they "induce cancer" within the meaning of the Delaney clause. Thereafter, the registrants filed requests for hearings, claiming that their rights to supply data and make legal and factual arguments against revocation and been violated. On June 30, 1994, EPA denied those hearing requests. Worse, EPA has also announced that it intends to revoke upwards of 70 additional tolerances in the same manner, presumably without affording the registrants an opportunity to defend their products in an administrative hearing.

Revise the Current "section 18" Policy. EPA's first act implementing the *Les* decision was not against the tolerances named in that case. Instead, EPA moved against the FIFRA section 18 "emergency" exemptions that farmers need to address unforeseen pest damage, for which alternative defenses often do not exist. On May 7,1993, EPA revoked five existing section 18 tolerances, and denied applications for 16 others because they "appear to meet" the Delaney clause "induces cancer" standard. This action was taken without actual findings that the residues in fact "concentrate" or "induce cancer" in violation of the Delaney clause, and without notice or opportunity for comment, as the FFDCA and the Administrative Procedure Act would require.

EPA acknowledged that its action would have an adverse impact on growers of up to $70 million in 1993 alone. Those losses, and impacts such as product "blacklisting" and loss of needed, effective products could have been mitigated if EPA had *first* (1) determined whether the residue actually violated the Delaney clause, (2) resolved the tolerances at issue in *Les*, or (3) addressed the issues then still pending in the NFPA petition. Instead, EPA embarked upon a course designed to create

the need for their particular legislative agenda, even saying boldly at the time that "The necessity of this [action] highlights the need for new legislation that addresses food safety. The Clinton administration will . . . develop a proposal." At that time, at least two separate proposals were already pending before Congress.

EPA could easily extricate itself from the massive administrative challenges it faces, avoid putting food production at risk, insure the public safety, and do so in full compliance with existing law and regulations if it were to:

- Grant the NFPA petition. Current concentration and coordination policies are illegal and no longer justified;
- Rescind its policy of intentional inaction.
- Abandon outdated policies (including definitions of "raw" and "processed" foods, and implementing the "flow-through" and "ready to eat" provisions of FFDCA), and redefining what "induces cancer" means for purposes of the Delaney clause;
- Stop regulating on the basis of exaggerated risks and assumptions;
- Grant the hearing requests sought by the registrants in the "*Les*" and subsequent tolerance revocation actions; and
- Rescind the Current section 18 policy, or make it applicable to only those products which in fact are prohibited by Delaney.

NACA'S RESPONSE TO S. 2084 AND S. 2050

NACA well appreciates the time, effort and attempts at inter-agency coordination which have gone into development of the administration's FIFRA/Food Safety proposal. However, by bringing omnibus new legislation to virtually every aspect of pesticide regulation, the bills amount to a wholesale overhaul. Rarely will a system which needs improvement be helped by adding layers and layers of untested new authority. By failing to focus on the areas of true concern, these bills will have the unintended affect of bringing the registration of new products (and the reregistration of existing products) to a halt, and they may not actually speed the removal pesticides found subsequently to exceed society's acceptable risk-benefit standard. They will, however, clog EPA and the courts with citizen suits and other litigation, and create confusion among EPA staff, the regulated community and public when EPA attempts to act under one or more of the multitude of new authorities.

Nevertheless, NACA will address each of the major components of the two bills, and explain why many of their provisions will not assist in the overall objective of improving the system of pesticide regulation, or the safety of America's food.

FFDCA AMENDMENTS (S. 2084)4

Risk Standard for Tolerances. Under the administration's proposal, a tolerance may be established for a raw or processed food if the residue is "safe." Safety is then defined as presenting "a reasonable certainty of no harm" when evaluating risks from cancer, risks other than cancer, and establishing tolerances for children and other sub-populations. Because it would fundamentally alter the standard for evaluating tolerances, the public deserves to understand precisely what this standard means, how it will be interpreted, and what the net effect will be on individual existing tolerances.

For instance, the definition of "safe" was taken from a section of the Code of Federal Regulations dealing with food additives. However, there is language in that definition which acknowledges that "intended conditions of use" are relevant, and that it is "impossible to establish with complete certainty the absolute harmlessness of the use of any substance." NACA is curious why the entire definition was not taken. Furthermore, the plain language of the phrase "no harm" appears to establish a zero-risk standard. If so, this bill merely replaces the Delaney clause with another "zero-risk" standard. While we appreciate that EPA has proposed replacing the Delaney clause with a single risk standard, NACA is very concerned with what this new standard means, and how it will be interpreted.

Finally, as this subcommittee knows, the current system for setting and maintaining tolerances is a "health-based" system. Consequently, the administration's increasingly vocal pleas for a "health-based" system are patently misleading. Pesticides are among the most heavily researched and regulated products on the market today. Before a pesticide may be registered for use, manufacturers must perform over 120 tests designed to protect human health and the environment. The registration standard requires protection of "human health," and pesticide tolerances are NOT set at particular levels in order to provide agricultural benefits. Although improvements are always welcomed (and have been continuously added under current law), we have a strong health-based system in place today.

Elimination of Benefits Consideration. Although the administration has never explained why limited consideration of benefits poses a public health concern, its bills preclude consideration of pesticide benefits when establishing tolerances and in regulating pesticide use. Although an extension of time for an existing tolerance may technically be grated using benefits, that extension would be virtually impossible to obtain. For instance, the registrant would have to show that loss of that particular tolerance would "severely disrupt domestic food production." Rarely, if ever, would loss of one product tolerance create a nationwide disruption. But over time, this provision could severely affect agriculture through the attrition of "a thousand paper cuts" which together would be devastating. Furthermore, proposals on so-called "label call-in" and "phase-down/phase-out" would eliminate consideration of pesticide benefits altogether.

Lost in both bills is the concept that decisions regarding risk cannot be accurately made without also evaluating the benefit which acceptance of that risk provides. A detailed consideration of benefits—which comes into play only when test results are very close to the safety standard—allows EPA to make informed decisions. After all, blind reliance on numbers alone is responsible for the Delaney dilemma we face now. Congressional debate concerning the value of a cost-benefit analysis in other legislation this year has shown that it is an extremely important undertaking.

Overly Restrictive Standards for Children and Sub-populations. Last summer's NAS report made several basic recommendations, including that more/better data be developed on pesticide use and on the foods children eat; that additional toxicity testing procedures be developed which evaluate the vulnerability of infants and children; and that improvements be made in the risk assessment process. NACA largely agrees with these recommendations, as does the 220-member Food Chain Coalition through the legislation which they support.

However, in subtle but important ways this bill goes beyond the recommendations of the NAS. For instance, the NAS recommended an additional 10-fold safety factor for infants and children for those instances where "there is evidence of postnatal developmental toxicity, and . . . data from toxicity testing relative to children are incomplete." By contrast, this bill requires the additional safety factor as a matter of course. The NAS report also did not suggest that EPA be required to make specific "findings" that tolerances are "fully protective" of infants and children. We question whether such a determination could actually be made, and fear that it will unnecessarily slow the review and approval processes without providing real, added protection, because EPA will be hesitant to certify that a tolerance is indeed "fully" protective.

Rather than first evaluating which of the NAS recommendations are already being done, which may be correct in concept but need more evaluation, whether methods exist to carry out the particular recommendations, and whether each recommendation provides added benefit or protection for the cost, EPA simply put the recommendations into legislative language. Although NACA understands EPA's desire to be responsive, blindly fixing each recommendation in legislation is dangerous because (as with the Delaney clause) it will prohibit EPA from adapting to changes in scientific understanding.

Exaggerated Exposure Assumptions. By requiring use of exaggerated exposure assumptions (100 percent of food contains residues at the tolerance level every day for a lifetime), EPA guarantees that its risk estimates will be vastly overstated. Although tolerances are set at the maximum use pattern (percent of crop, full label rate, etc.), this does not always result in residues at the tolerance level. Thus, these exposure assumptions would negate the use of actual or average residues, which have long been agreed to by almost everyone who has dealt with this issue. The administration's obsession with ultra-conservatism grossly overstates exposure, and makes no scientific sense.

Separate Tolerances. This bill allows EPA to establish separate tolerances for residues at any point in the food production chain. This new concept was merely alluded to in earlier testimony on the bill, and the language of the bill raises more questions than it answers. For instance, under what conditions and/or for what food forms would separate tolerances be required? Would separate tolerances be required for the same food at different stages in the distribution chain? What new or additional residue testing requirements would exist? And importantly, how will FDA conduct (and pay for) enforcement? Until these questions are adequately debated and answered, NACA believes this provision is premature.

No Uniform National Tolerances. This legislation fails to provide for national uniformity of tolerances. Without such uniformity, the varying laws of State and local governments will place an unfair burden on agriculture, food processing and transportation industries.

Tolerances for All Inert Ingredients and Metabolites. While failing to so acknowledge in previous testimony, the administration's bill will require a separate tolerance for each and every inert ingredient and metabolite in a pesticide product, regardless of toxicity. Under current law, EPA may chose to require a tolerance if the inert ingredient or metabolite presents a risk meriting such regulatory action. S. 2084 will require registrants to undertake massive additional testing and data development, and the data review will exhaust years of EPA staff time. By focusing scarce resources on real risk, the current system makes infinitely more sense.

Tolerance Reevaluation. This proposal requires EPA to review literally hundreds of existing tolerances and exemptions within 180 days, ad identify those which do not appear to meet the new standards. To maintain an "apparently unacceptable" tolerance, registrants would be required to submit data within 2 years; within 3 years EPA must make a final decision on 75 percent of those tolerances, and within 4 years for the remaining tolerances. Tolerances and exemptions which do not meet the new standard will be revoked.

In addition to the administrative burden, it is not at all clear how this new authority will relate to the reregistration program. Since EPA is currently making similar evaluations in that context, this additional authority is redundant. NACA members have already invested approximately $100 million dollars, and EPA has worked very hard to make reregistration a success. Failure to coordinate these efforts would be a shameful waste of both money and time. If tolerance reevaluation is not being adequately addressed through reregistration, then the solution is to fix that process, rather than creating a rival program in mid-stream.

Further, the task which EPA proposes is enormous, the deadlines strict, and the consequences (revocation) are severe. We believe EPA's self-imposed deadlines are unrealistic.

Unless EPA proposes to give the data only a cursory review, or adhere to a rigid numerical standard to determine whether a tolerance is safe, sufficient time simply does not exist to adequately analyze the data. We are also concerned that regulatory action (and "listing") will be initiated on what amounts to no more than whim. The proposed "appears to meet" standard is virtually unprecedented in its vagueness. Sufficient time will not exist in the 180 days following passage of the bill to set the standards and actually accomplish a review of all current tolerances and exemptions.

FIFRA AMENDMENTS (S. 2050)

Phase-Out/Phase-Down. Under this extraordinary new authority, EPA may restrict, reduce or eliminate the use or production of a pesticide if "credible scientific evidence indicates that use of the pesticide is reasonably likely to pose a significant risk to humans or the environment." The standard used in this section is vague, and the consequence of EPA action severe. For instance, does the "credible scientific evidence" trigger mean "some" evidence, or a preponderance of the evidence? What if that evidence was disputed by other "credible" evidence? Must "credible" evidence be peer-reviewed? These important questions are left unanswered in the legislation.

Other definitions which are unworkably vague are "reasonably likely to pose" and "significant risk." By "reasonably likely" does EPA mean any amount greater than 50 percent? By "significant risk" does EPA intend something less than or more than would be required to sustain a cancellation action? NACA also is concerned that the "use" of the pesticide which leads to risk does not contemplate that phase-out/phase-down would only apply when the pesticide was not being used "in accordance with widespread and commonly recognized practice" as is currently required under FIFRA.

This authority is also redundant with both current and proposed new authorities. For instance, if EPA discovered a new risk, why would existing cancellation and/or suspension authorities not suffice? If cancellation or suspension are inadequate, why not amend them? Regarding the proposed new authorities, it is unclear when EPA would choose to proceed with a data call-in, label call-in, phase-out/phase-down, prescription use, cancellation, or suspension authorities.

In a final irony, this legislation expressly prohibits common-sense application of the phase-out/phase-down authority. This bill prohibits EPA from taking into account differences between various classes of pesticides, differences in environmental risk, and differences between agricultural and nonagricultural pesticides. At a time when the entire production of a pesticide could be eliminated, these considerations are extremely important. Because it ignores the significant investment of time and money which registrants make in their products, tramples the fundamental due process rights necessary to challenge unfounded government action, and denies a

company the ability to legally produce basic chemicals—possibly for other uses—NACA strongly opposes this provision of the bill.

Cancellation Procedures. Under S. 2050, FIFRA's current formal cancellation procedures would be replaced by informal rulemaking, a process which provides none of the procedural protection necessary to adequately defend a product's registration. Whereas the cancellation process under current law allows an adversely affected party to request an adjudicatory hearing (involving an opportunity to present testimony and cross examine witnesses before an impartial decisionmaker), the informal rule making proposed here is little more than the familiar "notice and comment" process.

In the past, EPA has argued that disregarding these procedural protections is justified because the formal hearing process is "too burdensome." However, since 1980, EPA has issued approximately 40 cancellation notices under FIFRA, and a hearing with cross examination was requested in only three of those proceedings. Testimony in those hearings averaged only 21 days. Although S. 2050 does allow an affected party to request an *informal* hearing, EPA may decline to hold the hearing. If held, the hearing would not allow for cross examination or other procedures which provide important due process rights. As such, the protection offered is inadequate to a full and fair evaluation of agency action.

In addition, the burden of proof in a cancellation proceeding is inexplicably shifted from the challenger to the registrant, who must show why a cancellation should not go forward. This turns the concept of fundamental fairness on its head. Once EPA has granted a registration, having reviewed all required data, it is only fair that the party initiating a cancellation should have the burden of showing the standard for cancellation has been met.

Finally, this bill changes the standard for challenging agency action in court from whether the action is supported by "substantial evidence" to whether the action was "arbitrary and capricious." Particularly when combined with the inability to enter testimony and examine witnesses, this change is significant. By stacking the deck entirely in favor of the Agency, EPA has effectively eliminated a registrant's ability to defend its products.

To the degree data show that current procedures-are inadequate or do not protect the public health, NACA has been willing to support improvements. However, the wholesale revisions contained in this bill have stripped all that is fair from the process, making a cancellation under this process a *fait accompli.* For those reasons, NACA opposes them.

Suspension by Order. Similar to the proposed cancellation language, S. 2050 would replace current suspension procedures with "suspension by order." In short, this proposed process eliminates the expedited hearing (including the opportunity to present evidence and examine witnesses on the record), allows EPA to proceed without simultaneously filing a notice of intent to cancel, and lowers the standard for challenging agency action from "substantial evidence" to "arbitrary and capricious."

Particularly in light of the proposed cancellation amendments, NACA questions the need for such drastic change. If cancellation is expedited, what value is there to changing suspension? Since 1972, EPA has suspended the registration of only five pesticides. One explanation why suspension may not have been used more often is that improved registration requirements, reregistration, and existing cancellation and other regulatory authorities have avoided pesticide emergencies and "imminent hazards." EPA should first be required to show how current law has failed to protect the public health, and specifically, how current suspension authority is inadequate. This is especially true, since FIFRA amendments in 1988 were designed *specifically* to address weaknesses in EPA's ability to use its suspension authority. If deficiencies remain, then they should be fixed in a manner which is tailored to addressing a particular need. Rather than seeking specific improvements, the cancellation and suspension provisions offered under S. 2050 abandon virtually *all* of the concepts of fairness in current law, in favor of a process which focuses only on administrative expediency for the Agency.

Label Call-In. In testimony before Congress last September (and when soliciting support for its proposal), EPA cast its label call-in proposal in terms of "relatively small changes" such as "additional warning statements." However, when reduced to legislative language, the proposal encompassed wholesale changes in labeling, packaging and even composition of a pesticide. Under S. 2050, EPA is authorized to order such changes if the Administrator "determines that the risks associated with the use of a pesticide can be reduced." The only limitation on EPA's authority would be if the change effectively prohibits or makes economically unfeasible substantially all use of the pesticide on one or more use sites.

The concepts of "cost" or corresponding "benefit" have not been linked to the particular risk reduction effort. (The only mention of cost is to "society" at large, which is meaningless in the context of specific agency action.) For instance, assume that EPA determines that risk could be reduced by eliminating aerial application or by a different type of formulation. Would not the cost of such changes, and the amount of benefit from the changes, be relevant considerations? By failing to include these, or some form of "least burdensome" requirement, the administration has given itself unnecessarily broad authority and placed an unnecessary burden on registrants, users and dealers, and the public at large.

Registration Renewal ("Sunset"). S. 2050 recasts FIFRA's current reregistration program as a system where pesticide registrations must be reviewed and renewed every 15 years. To accomplish this, registrations would be divided into three categories: pre–1984, post–1984, and postamendments. Each category would have staggered deadlines for EPA to complete its review. By the deadline, EPA must let the registration expire because the application is incomplete or supported by insufficient information, renew the registration, or initiate a cancellation proceeding. If EPA fails to act within the prescribed timeframe, the registration may receive an extension of one additional year. Fees paid by registrants would support this program.

While NACA understands that some type of periodic review makes common sense, we have fundamental concerns the content, structure and scope of this proposal. First and foremost, we believe that any successful review or renewal effort must be built on first completing the existing reregistration program. Once that program is complete or substantially complete, all interested parties should review the program shortcomings, to avoid repeating any of the initial program mistakes. The reregistration has already taught that (1) there must be certainty, at the beginning, on what constitutes a complete data package, (2) EPA must be realistic in the time it takes and allows the registrant to develop the required data, and (3) EPA must allow itself sufficient time and resources to analyze that data properly. This proposal learns from none of those lessons. By setting strict deadlines in legislation, without first estimating which or how much data will be required or submitted, or the time and resources necessary to review that data, EPA is setting itself up for failure and fiber loss of public confidence. Because of the strict, possibly unrealistic deadlines, product registrations which actually meet the existing standards will be put at unnecessary risk.

We also fail to see how this process coordinates with timetables and existing or proposed authorities regarding tolerance decisions. Without careful coordination, tolerance and registration decisions will not be consistently reviewed, resulting in wasted time, money and effort. Without careful coordination and honest evaluation of the ongoing reregistration program, this proposal threatens to disrupt public confidence, and what is universally recognized as the safest, most efficient and productive food safety and production system in the world.

Reduced Risk Pesticides. S. 2050 directs EPA to develop criteria for designating a pesticide as "reduced risk." Registration applications which meet the criteria would be eligible for priority review, and if other conditions are met, would receive two additional years of exclusive use of data. That this provision even exists is proof that it takes too long to bring new pesticide products to market. It is unacceptable that even simple applications can take over 2 years after all necessary data has been submitted. If *all* applications were reviewed and acted upon with reasonable speed, "priority review" would not be necessary. NACA would prefer that EPA find ways to speed the existing registration system, rather than speeding the system only as a "bonus."

On its face, this provision has certain appeal because the public wants (and EPA would be able to claim it is approving) "safer" pesticides. We ask "safer than what?" If all products registered are indeed "safe" (having submitted data and "passed" some 120 different tests required under FIFRA) this bill establishes a two tier system. Rather than increasing public confidence, this provision will actually increase public fear, because (if the program is successful) the number of "safer" pesticides will always be fewer than the "other" pesticides. Importantly, this bill also fails to recognize that once registered under FIFRA, all pesticides have shown themselves to be "safe."

We also question whether it is truly possible to develop criteria which fairly determine which pesticide is "safer" than another. Will safety be judged to the applicator or consumer? Is one form of application "safer" than another? What about pesticides which clearly decrease the risk in one area, but arguably increase risk in another? We raise these questions because we know how difficult it will be for EPA to fairly develop criteria and administer the program. There is no question that we all want "safer" pesticides. The only question is how to develop and bring them to market.

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New products and technologies, and those currently "in the pipeline," prove that the market is already quickly moving in that direction. However, until we understand what standards and criteria EPA intends to use to implement this program, and until more experience is gained through EPA's current "pilot program," we believe that legislation on this subject would be premature.

Fees. In addition to the fees imposed for tolerance review and approval activities under S. 2084, S. 2050 imposes at least five new user fees. New fees are assessed for registration renewal ("sunset"), exports, new supplemental reregistration fees (except for biological pesticides and minor uses), an extension of the annual maintenance fees, and a new fee on pesticides eligible for reregistration.

NACA is sympathetic to the resource demands upon EPA. However, in spite of repeated requests for an accounting of the millions of dollars already paid to support reregistration, EPA has failed to provide any such document or report. Nevertheless, NACA member companies have continued to honor the fee structures put in place through FIFRA '88 and its amendments. It is most disturbing that there is no evidence in this legislation, or in testimony to date, that the administration has made even a token effort to estimate how much any of these new programs and authorities will cost. In fairness, registrants cannot be expected to come to the table with a blank check, and receive no guarantee that their investment is sufficient, or is being well managed. As new sources of revenue are discussed, industry and government alike must honestly address the cost to fully find existing programs, the additional cost to find new programs, and then carefully evaluate the incremental benefits derived from that added cost.

Prescription Use. For pesticides classified under the "restricted use" provisions, S. 2050 would allow EPA to impose a condition that the pesticide be applied only by prescription. While the goals behind the provision are worthy of discussion, NACA doubts that sufficient structures are currently in place to ensure that such a system could currently be administered fairly and effectively, and without significant disruption of agricultural practices. Adequate statutory guidance (absent in this proposal), and available and affordable commercial services are absolute prerequisites to a workable prescription use plan. At present, this proposal is at best premature.

Citizen Suits. S. 2050 would authorize any person (with or without a financial interest in the matter) to bring suit in Federal Court against EPA, a pesticide registrant, or any pesticide user except for certain agricultural producers engaged in production, for any alleged violation of FIFRA or any EPA pesticide regulatory requirement. However, a citizen may make a request (not subject to judicial review) that the Administrator or a State, take action against a producer. Provisions exist for the payment of attorney fees, expert witness fees, and litigation costs to any party who "substantially prevails." NACA believes that this is an invitation for gridlock. We fail to see how this provision is consistent with the administration's goals of reinventing government, or of forging a partnership with the regulated community.

Civil and Criminal Penalties. Current civil penalties for registrants, commercial applicators and distributors of $5,000 per violation are increased under S. 2050 by 500 percent, to $25,000 per day, up to a maximum of $400,000. Furthermore, the current warning requirement prior to imposition of a fine has been eliminated. For criminal penalties, current law provides or fines (maximum of $25,000) and jail (maximum 1 year) for knowing violations by registrants, commercial applicators and distributors. S. 2050 not only increases the fines (to $50,000), but also makes them per day, and allows for double fines for second violations. Jail time is also increased from 1 year to 5 years. However, by far the most troubling aspect is that the standard for any violation of FIFRA has changed from a knowing violation to merely a negligent violation.

NACA agrees that EPA should have strong, meaningful authority to punish intentional violators, as well as repeat offenders. But we question, on grounds of fundamental fairness, whether such unprecedented, stringent authority (particularly as applied to smaller, commercial applicators or dealers) is necessary to deter negligence. The proposed scheme establishes virtual strict liability, with severe penalties. We wonder if improved training and education are not better approaches to decreasing actual risk and protecting the environment. This approach is also more consistent with the administration's goal of reducing pollution at its source. This proposal, on the other hand, is clearly designed for its punitive effect.

Inspection and Record Keeping. Under current law, EPA has authority to require pesticide producers to maintain certain records (FIFRA Sec. 8), and to inspect establishments where pesticides are held for sale or distribution (FIFRA section 9). S. 2050 expands both authorities, to require and inspect records of distributors, pes-

ticide testing facilities, commercial applicators. EPA would also have new authority to inspect pesticide user premises and pesticide testing facilities. Inspection of private residences and farms would be limited to instances of "suspected violations." In addition, EPA would have the authority to require record keeping for all agricultural pesticide use.

Of these provisions, and many other not listed, NACA is most concerned about inspection of private residences without a warrant. If a "suspected violation" is enough to initiate a search, and refusal (even on good faith grounds) to consent to a search constitutes a separate violation, it is not difficult to imagine that an anonymous complaint (whether founded or not) could lead to $25,000 or more in penalties against a farmer who refuses to consent to a warrantless search. We believe the administration's proposal is rife with such possibilities, and represents a dangerous incursion into the privacy and personal liberty of its citizens.

Nevertheless, NACA understands, and has no objection to the administration's desire to encourage safe production and use of pesticide products. We believe that a system where everyone adheres to the highest level of professionalism serves the regulated community, the regulators, and the public. However, when seen in light of the new civil and criminal penalties (particularly for negligent violations), these requirements are ominous. As with the penalty provisions, a system which educates and rewards compliance would be infinitely preferable.

Exports. Under new regulations put in place during this administration, any pesticide made in the United States (including unregistered pesticides) may be exported as long as it is labeled in accordance with EPA regulations and the exporter receives from the foreign purchaser a written acknowledgement of the pesticide's unregistered status. Under S. 2050, export of pesticides banned for use in the United States would be prohibited, subject to two narrow exceptions. As we have testified repeatedly in the past (and will elaborate on if you desire), we believe that current law is working well, that these restrictions are unwarranted, and that further restrictions will drive jobs, production and research out of the United States.

Further, the proposal to raise $4 million through a find which amounts to an export tax for foreign technical assistance programs is simply a bad idea. To our knowledge, no other country taxes its own exports—for any reason. Further, these programs would be largely redundant, duplicating many of the product stewardship efforts already in place and/or in development by many NACA member companies.

Conclusion

Mr. Chairman, we sincerely wish we could tell you that this bill could easily be fixed. It cannot. By creating too many new authorities with vague and ambiguous standards and triggers, failing to coordinate with existing authority, and generally operating without adequate due process protection, NACA cannot offer its support. As we have said repeatedly in the past, NACA does stand ready to work with this committee and any other interested party. We believe that starting with S. 1478, a bill with the support of 22 cosponsors, offers the best possibility for real reform.

Philip J. Landrigan

Mr. Chairman, and Members of the subcommittee, my name is Philip J. Landrigan, M.D., M.Sc. I am professor and chair of the Department of Community Medicine and director of the Division of Environmental and Occupational Medicine of the Mount Sinai School of Medicine in New York City. Also I am a pediatrician and professor of Pediatrics at the Mount Sinai School of Medicine. Formerly I was a member and then the chair of the Committee on Environmental Hands of the American Academy of Pediatrics.

From 1988 through 1993, I was the chair of the National Research Council (NRC) Committee on Pesticides in the Diets of Infants and Children. This committee issued its final report in June 1993, and at the time of release of that report I and other members of our committee had the honor to present testimony describing our findings and recommendations before the Full Senate Committee on Agriculture. I have also collaborated with more than 30 pediatricians, public health specialists and other physicians convened-by Physicians for Social Responsibility to develop and support legislation to implement the recommendations of the NRC report.

I am pleased to appear before you today to discuss issues relating to the reform of pesticide policy in the United States. As a pediatrician, I believe that the subject of this legislation is of great significance to the health of all of America's children.

The NRC Pesticide Report

Last year's NRC study concluded that the Federal Government's decisionmaking process for regulating pesticides in the diet does not pay sufficient attention to the

protection of human health, especially the health of infants and children. The Government's current pesticide regulatory program takes a one-size-fits-all approach. It ignores the great diversity in diet that exists among people of different age groups, and fails to take cognizance of the fact that children differ greatly from adults not only in their size but also in their metabolism and in what they eat.

A fundamental tenet of pediatric medicine is that children are not just little adults. They are in many respects truly different. Unfortunately, current pesticide regulation in the United States does not adequately reflect that understanding. Today's regulatory system does not specifically consider variations in pesticide exposure between adults and children. Neither does it consider the ways in which children's bodies may react differently to foreign substances.

To better protect the health of infants and children, the NRC report recommended that the Federal Government change some of its scientific and regulatory procedures for limiting pesticide residues in children's diets. It also recommended that the regulatory agencies adopt a new method of risk assessment to more accurately gauge the population at risk. And it urges that toxicity testing of pesticides be more comprehensive.

The goal of our report was to make the very good food supply of the United States even better. We did not say that parents should radically change their children's diets to avoid certain foods. On the contrary, parents should continue to emphasize fruits and vegetables in their children's diets. Nonetheless, basic changes are needed in the current regulatory system to ensure that foods eaten by infants and children are safe.

Tolerances—the levels of pesticide residues legally allowed on or in foods when they leave the farm—constitute the only mechanism for regulating pesticide residues in foods. Thus our committee recommended that the Government have as its clear goal the setting of tolerances that more fully protect human health, including the health of infants and children.

Children tend to eat fewer kinds of foods as compared to adults and they consume more of certain foods per unit of body weight. In addition, they drink more water, both alone and mixed with other foods. For example, children under the age of 6 months consume 7 times more water pound per pound of body weight than do adults. The current regulatory system does not consider these differences. Neither does it do a good job of considering the differences in diets between children of different ages, ethnic backgrounds, and regions of the country.

The NRC Committee suggested a new approach to pesticide risk assessment and thus to tolerance setting that would look at the diets of infants and children separately from those of adults. Current risk assessments use a single number to represent the average exposure to pesticides of the entire American population. But this method overlooks children on both ends of the spectrum—those who receive above-average exposure as well as those who receive below-average exposures. We recommended, instead, a statistical technique that combines data on the kinds and quantities of foods eaten by children with data on the pesticide residues on those foods. This combined analysis would help regulators determine actual exposure levels is for children in a variety of circumstances, rather than looking only at average exposure. It would provide a rational basis for setting more effective tolerance levels.

The NRC Committee noted that a major obstacle to the use of this new approach is a lack of data in certain areas. Clearly, more accurate risk assessments will not be forthcoming without better information on food consumption patterns, pesticide residues, and toxicity. Specifically, the NRC Committee recommended that measurements of pesticide residues in foodstuffs should be standardized across the Nation and computerized. These measurements need to reflect foods eaten by children, the different rates and methods of pesticide applications and the effects of food processing on pesticide application, and the effects of food processing on pesticide concentrations.

The NRC Committee recommended that regulators must take into account children's exposure to pesticides from nondietary sources. Water, air, soil, lawns, and indoor surfaces all must be considered as potential sources of exposure.

The NRC Committee urged regulators to recognize that children may be exposed to multiple pesticides with common toxic effects. The NRC report recommended that EPA treat pesticides that are pharmacologically related or have a common toxic mechanism or effect as being additive in their action in the absence of evidence to the contrary.

The NRC Committee recommended that toxicity testing procedures should be developed that specifically evaluate the vulnerability of children. Of particular importance are tests for toxicity to the developing immune, nervous, and reproductive systems.

The NRC report recommended that there should be a presumption of greater susceptibility of infants and children in the absence of evidence to the contrary. Currently, if animal tests show no adverse effects for a pesticide at a certain exposure level, then the level that is thought to be safe is determined by dividing that no-effect level by 100. This accounts for differences between humans and animals as well as variation among humans. EPA then divides this number again by 10 if studies have shown effects on the developing fetus. The NRC report recommended use of an additional 10-fold safety factor to account for differences between adults and children.

Finally, the NRC Committee recommended that estimates of disease risk from pesticides take into account changes in exposure and susceptibility that occur throughout a person's life. Children who are exposed to a carcinogen early in life have many more years of life ahead of them than do adults to manifest a cancer or other chronic illness that may be triggered by early exposure. Risk assessment procedures and the standard setting process need to take cognizance of this biological difference. This difference constitutes an further rationale for the NRC recommendation of an additional 10-fold safety factor.

THE ADMINISTRATION PROPOSAL

Overall, the administration's pesticide reform proposal is well intentioned and incorporates many of the recommendations of the NRC Committee, but lacks key details. The administration's general emphasis upon the special sensitivity of children to pesticide residues is overdue. Elements of the administration's proposal are worthy of specific praise. Thus, the administration proposal for better data collection on foods infants and children eat, pesticide residues in those foods and for paying attention to differences in sensitivity to these residues, will enhance our understanding of the full range of toxic effects of pesticides. Also the administration's call for wider application of health standards to raw and unprocessed food and expanding food safety testing from the farm gate through the retail level will be very useful.

In at least three specific areas, however, the administration proposal makes note of, but fails to fully implement the recommendations of the NRC Committee. In each of these important areas—standard setting, multiple exposures and specific testing protocols—the administration's good intentions are undermined by excess discretion or by a willingness to allow a lack of information to perpetuate unnecessary exposures of children to pesticides. In each area, applying a more protective presumption against continued pesticide exposures would more accurately reflect the preventive public health recommendations of the NRC Committee and more effectively reform Federal pesticide policy.

STANDARD SETTING

Acknowledging the particular vulnerability of infants and children to pesticides, the administration proposal includes up to an additional 10-fold margin of safety for pesticide residues. Superficially, this provision would appear to implement the recommendation of the NRC Committee. But the administration proposal merely suggests that the additional 10-fold margin of safety "take into account . . . the completeness of the data with respect to infants and children." By contrast, the NRC more explicitly prescribed the additional margin of safety "when data from toxicity testing are incomplete." The administration proposal should specify that the additional margin of safety shall be applied, unless there exists evidence that it is unnecessary.

MULTIPLE EXPOSURES

The administration proposal notes that EPA "shall fully account for available information on the cumulative effect of such residue and any chemically or pharmacologically related substances in the human diet, and other ways in which the consumer may be exposed to such residues . . . including, to the extent data permit, through drinking water." More specifically, the proposal would require EPA to "assess the risk of the pesticide chemical residue based on . . . available information concerning the cumulative effects on infants and children of such residues and other substances that have common mechanisms of toxicity."

Although appearing to satisfy the NRC recommendation, this component of the administration proposal falls short because it would continue to allow a pesticide the benefit of the doubt if toxicity testing for combined action has not been undertaken. To fully implement the NRC recommendation, the administration proposal should prevent unnecessary childhood exposure to pesticide residues by requiring EPA to treat pesticides that are pharmacologically related or have a common toxic

mechanism or effect as having an additive deleterious effect, in the absence of evidence to the contrary. This provision—omitted from the administration proposal—would implement the NRC recommendation that in the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children.

CHILD-SPECIFIC TESTING PROTOCOLS

Although the administration's proposal seeks additional data on the effects of pesticides on children, it requires no specific protocols for tests to assess whether a pesticide poses particular risks to children. The administration proposal would require collection of additional data only for general determinations of whether a pesticide might compromise the "special vulnerabilities of children and other sensitive populations." By contrast, the NRC Committee endorsed more ambitious testing protocols to better protect children from unnecessary pesticide exposures. Legislation should require EPA to develop protocols for tests that would specifically determine whether a pesticide poses particular risks to infants and children. This provision—omitted in the administration proposal—would ensure that pesticide data submitted to EPA satisfy children-specific safety requirements.

Summary

In summary, children deserve special consideration when it comes to pesticide regulation. By including some of the specific recommendations outlined in the NRC report, the administration pesticide reform proposal would advance our understanding of the risks infants and children face from pesticide residues. In several important respects, however, the administration proposal—while echoing the language of the NAS report—would not ensure that the report's recommendations would be fully adopted. By more firmly implementing the NRC's recommendation of a protective presumption against continued exposure to pesticide residues, the administration and Congress could do much to ensure that children's health is not compromised and that America's future is conserved.

Mr. Chairman, I shall be pleased to answer any questions.

Stephen A. Ziller

Mr. Chairman, and Members of the subcommittee, I am Stephen Ziller, the vice president for Science and Technology of the Grocery Manufacturers of America (GMA). I am appearing today on behalf of GMA to testify on Federal regulation of pesticides that are used in the production of food.

GMA is an 85-year-old national trade association comprised of over 130 companies which manufacture food and other products sold in retail stores throughout the United States. Member companies employ over 2.5 million people nationwide and have annual sales in excess of $360 billion. Our members produce more than 85 percent of the packaged food sold at retail in the United States.

For almost two decades, GMA has supported the concept of revising the statutory provisions governing Federal regulation of pesticides used in the production of food. That support has, of course, been conditioned upon new legislative provisions that would strike an appropriate balance between preserving an abundant and wholesome food supply and protecting against unsafe pesticide residues.

An unusually large member of bills are now pending before Congress that would change the way that EPA and FDA regulate pesticides. Rather than address any particular bill, my testimony will deal with ten general principles that GMA believes are essential to any successful legislative approach to revise the current statutes relating to Federal regulation of pesticide residues in food. GMA is committed to support legislation that embodies these principles, and we will oppose legislation that fails to reflect these principles.

1. *National Uniformity.* It is essential that any new legislation establish a single national policy for the regulation of pesticides used in food production. We cannot tolerate a system under which each of 50 different States can have its own separate requirements. The food industry cannot market 50 different products in this country, one for each State. Without national uniformity, no legislation relating to pesticide residues in food can be acceptable to GMA and its members.

2. *Safety of Pesticides.* New legislation should require pesticide tolerances to be established at a level that will adequately protect the public health. For a carcinogen, we support the use of reasonable risk assessment procedures to assure that there is a negligible risk. Human exposure assessments should be based on actual data whenever possible, and where such data are lacking on the basis of reasonable

assumptions. It is inappropriate and scientifically unacceptable to establish detailed rules for safety assessment in legislation, because science changes so quickly that the legislation simply cannot keep up with it. EPA must be entrusted to use the best available safety assessment procedures as they are developed and become accepted within the scientific community. Arbitrary and rigid rules, such as specific safety factors, frozen into law, are incompatible with sound scientific decisions.

3. *Benefits of Pesticides.* Any new legislation must reflect the fact that pesticides play a major role in the production of a safe and wholesome food supply and thus provide substantial benefits to the American public. Pesticides control disease and preserve an adequate and affordable food supply. It is therefore important that any new legislation reflect these important benefits.

4. *Periodic Review of Pesticide Tolerances.* GMA has no objection to the periodic review of pesticide tolerances, to assure that the tolerances continue to reflect adequate protection of the public health in light of new information. There should be no set time for this review, no penalty for the failure of EPA to conduct such a review, no need for a formal proceeding where none is justified, and no sunset on tolerances where a review is not justified and thus not undertaken. Arbitrary timetables and schedules must be avoided. It is sufficient to authorize periodic review within EPA priorities and resources. Experience shows that arbitrary schedules set by legislation are invariably unrealistic and cannot be met. Legislative schedules impose political priorities upon a Federal agency that do not necessarily represent sound scientific priorities. Wise public policy requires that EPA be free to take all scientific information into account in establishing its priorities for periodic review.

5. *Phasing In the New Legislation.* It will take time for EPA to assimilate the new legislation into its existing systems, to propose and promulgate regulations, and then to begin to implement the changes that are made to existing law, policy, and procedure. This cannot be done immediately or according to a rigid timetable set by Congress. It must be done according to scientifically based priorities established by EPA itself. Rigid timetables imposed by legislation will not represent true scientific priorities and will ultimately be unworkable.

6. *The Food Pipeline.* The presence of pesticides in the food chain occurs not at a single point in time, but over many years. A pesticide can be applied to a food today, the food may be processed a year or more after that, the processed food becomes available to consumers still later, and it can remain in the marketplace and kitchens throughout the country for many years. It is possible to stop using a pesticide, or to reduce pesticide use, on the farm at any particular point in time, but nothing can be done to remove or alter the pesticide residues that exist from prior legitimate use on food that has already entered the food pipeline. Appropriate legislation must therefore reflect that food containing pesticide residues that were lawful at the time of use must remain lawful throughout the subsequent life of that food unless new information demonstrates a serious health hazard. Any failure to do this would represent an extraordinary disruption in the food supply.

7. *Scientific Peer Review.* Under present law, the cancellation of a pesticide tolerance can be challenged in a formal trial-type administrative hearing that is both costly and time-consuming. GMA supports the use by EPA of scientific peer review to resolve issues relating to pesticide tolerances before EPA makes a final cancellation decision, in place of a trial-type hearing after that decision has been made. Consistent with the view that all aspects of pesticide regulation must be based on sound science, GMA strongly believes that the use of scientific peer review to resolve tolerance issues will greatly enhance the ultimate decision. New administrative approaches such as phase-out/phase-down and label call-in are not justified. Suspension and cancellation are sufficiently flexible procedures to permit EPA to apply new information to existing pesticides.

8. *Enforcement.* Both EPA and FDA currently have extraordinarily strong enforcement authority that is more than adequate to implement any new pesticide legislation. New enforcement authority for EPA and FDA will preclude industry support of legislation. Citizen suits and whistleblower provisions are extraneous to pesticide legislation and cannot be justified. Any legislation with enforcement provisions of these types will be vigorously opposed.

9. *International Harmonization.* International scientific bodies also review the safety of pesticides and establish tolerances for pesticide residues in food. The United States officially participates, for example, in the Codex Alimentarius Commission, which undertakes this task on a worldwide basis. New safety legislation should therefore require that Codex determinations on pesticide safety be taken into consideration by EPA, and that EPA explain any difference between the tolerances that it sets and the determinations that are made by Codex.

10. *User Fees.* Federal regulation of pesticides should be accomplished by EPA and FDA out of general appropriations, not from special taxes imposed on the regulated industry. Pesticide regulation is intended to benefit the entire American public, not just some small segment of the pesticide and food industries. User fees would represent nothing more than a poorly disguised tax on food.

Conclusion

It is important to pare down pesticide legislation to the bare essentials, if it is to be supported by the food industry. These ten principles establish the GMA position on these matters. The legislation introduced by Representative Lehman (H.R. 1627) and Senator Pryor (S. 1478) meet these general principles, and we support that legislation. The legislation recently introduced by the administration violates virtually all of these principles and we strongly oppose it.

Juanita Duggan

Mr. Chairman and Members of the subcommittee, I am Juanita Duggan, senior vice president for Government Affairs of the National Food Processors Association (NFPA). NFPA appreciates the opportunity to appear today and to address the important topics of pesticide regulation and food safety. We commend the Chairman's leadership in holding a hearing on pesticide reform legislation and in providing a forum for discussion of the critical pesticide policy choices facing EPA.

NFPA is the Nation's largest food trade association, representing the $400 billion food processing industry. Our 500 member companies include food processors and food packaging and equipment manufacturers. NFPA maintains and operates three research laboratories, employing more than 80 Ph.D.'s and other scientific personnel involved in a wide range of food processing research, including pesticide residue analysis and investigation.

NFPA represents the vast majority of fruit and vegetable processors in the United States, including processors of many minor crops. Consequently, NFPA has a vital interest in pesticide regulatory procedures and food safety standards. NFPA strongly supports programs to develop economical and effective alternatives to pesticides. The food processing industry is making concerted efforts to develop alternatives pest control techniques, including biological, cultural and mechanical controls, to support integrated pest management (IPM) programs and to minimize pesticide use. NFPA supports further research and funding of these efforts, as well as steps to facilitate EPA registration of effective biological control agents to further reduce pesticide use. It is important to recognize, however, that, even with ongoing efforts to reduce pesticide use, the responsible use of pesticides will continue to be necessary for the production in the United States of an adequate, wholesome and nutritious food supply.

Consistent with the recommendations of the 1987 National Academy of Sciences (NAS) "Delaney paradox" Report, NFPA supports statutory changes to establish a uniform negligible risk standard for pesticide tolerances for raw and processed food, and to give EPA sufficient authority to take into account the best available scientific information in tolerance decisions. The Ninth Circuit Court of Appeals Decision in *Les* v. *Reilly* confirms the need for legislation giving EPA additional flexibility in tolerance decisionmaking in light of modern advances in safety testing and risk assessment methodology.

NFPA supports reasonable efforts to reform the pesticide regulatory process, as well as to resolve the Delaney paradox. We support legislation that streamlines the procedure for removing hazardous pesticides from the market, promotes sound scientific judgment in pesticide tolerance decisions, assures that tolerance decisions are based on accurate exposure data, requires renewal of pesticide tolerances to assure compliance with current safety standards, facilitates minor use registrations and provides for national uniformity of pesticide tolerances.

Consistent with these objectives, NFPA strongly supports S. 1478, introduced by Senators David Pryor and Richard Lugar, and its counterpart the Lehman-Bliley-Rowland bill (H.R. 1627), which has broad bipartisan support in the House. We believe these bills provide the best vehicle for pesticide reform. These bills would make important improvements in both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFD&C Act). They would streamline the pesticide cancellation and suspension processes, establish a consistent negligible risk standard for pesticide tolerances for raw and processed food, assure appropriate consideration of pesticide benefits and provide for national uniformity for tolerances meeting current safety standards. Moreover, S. 1478 contains specific provisions, which we strongly support, that would require EPA to im-

plement recommendations described within the recent NAS Report on Pesticides in the Diets of Infants and Children.

The strength of S. 1478 and H.R. 1627 are reflected by the fact that they are endorsed by a broad coalition of food industry organizations, including growers, processors and retailers, and have attracted solid Congressional support, with 20 Senate co-sponsors and 222 House co-sponsors. The bills provide a solid foundation from which to enact reasonable food safety legislation.

The administration recently released its own legislative proposals for pesticide reform. The focus of my testimony this morning will be to explain why NFPA supports S. 1478 and H.R. 1627, rather than the administration's proposals. The administration's bill would restrict, rather than enhance, EPA's ability to employ the best scientific evidence in tolerance decisions. Moreover, the administration's bill would go far beyond reform of pesticide tolerance standards, as recommended by the NAS, and would eliminate consideration of pesticide benefits, revise most major FIFRA procedures to reduce public participation rights and scientific review requirements, grant multiple additional enforcement powers to EPA and FDA and authorize citizen suits in a variety of contexts. There is no demonstrated need for such a total overhaul of FIFRA. Moreover, the administration's bill does not address an issue of critical importance to the food industry; national uniformity of pesticide tolerances. The broad, sweeping amendments in the administration's bill are contrary to the interests of the food industry and consumers, and would serve to accelerate the loss of safe and effective minor use pesticides, which are of particular importance to our members.

We have made it clear that we support a uniform negligible risk standard for pesticide residues in raw and processed food, but *not* at the expense of scientific reason, regulatory order and consumer welfare. It makes no sense to replace the Delaney clause with an equally rigid and arbitrary safety standard, to superimpose a different tolerance reevaluation schedule on top of the FIFRA reregistration process, to abandon consideration of benefits in tolerance decision or to impose further data requirements and cost pressures on minor uses.

The administration has argued that immediate legislative action is needed to avoid the potential "crisis" created by the Ninth Circuit Court Decision in *Les* v. *Reilly*. The Agency would have the Congress believe that unless immediate legislative changes are made the Agency will have no choice but to revoke tolerances for a large number of valuable pesticides with serious adverse consequences for agriculture and the food industry. In fact, however, the Agency's hands are not tied by *Les* v. *Reilly*. EPA has sufficient authority under existing law to regulate pesticide tolerances in a manner that would minimize the impact of the Delaney clause, and there is no need to consider food safety legislation in a crisis atmosphere.

The potential devastating loss of agricultural pesticides threatened by EPA is not a necessary result of the *Les* v. *Reilly* decision but of EPA's concentration and coordination policies. These policies are an EPA invention that has never been properly adopted as a regulation and should be abandoned. EPA's concentration policy requires issuance of a section 409 food additive tolerance whenever there is a possibility that a pesticide residue might concentrate in a processed food and its coordination policy mandates that, if a section 409 tolerance cannot be issued (because of the Delaney clause or otherwise), EPA must also revoke the section 408 raw product tolerance and cancel the underlying pesticide registration for the pesticide.

In September 1992, NFPA, the United Fresh Fruit and Vegetable Association and other groups filed a petition urging EPA to rescind its concentration and coordination policies and no longer to require separate 409 tolerances for pesticides in processed food. The NFPA petition urges EPA to follow the language and intent of the "flow-through" provision of the FD&C Act, which provides that a pesticide residue in processed food when ready to eat is lawful as long as the residue is not greater than the tolerance for the raw commodity from which the processed food is made. The NFPA petition demonstrates that the EPA policy was never envisioned by Congress, and is based upon erroneous factual assumptions. Extensive data submitted in support of the petition show that actual residue levels in agricultural commodities and in processed food are well below raw product tolerances. The petition demonstrates that continuation of current EPA policy will require numerous costly tolerance revocation proceedings, will force the Agency to prohibit the use of beneficial pesticides that pose trivial risks and will thereby reduce the availability and increase the cost to consumers of nutritious fruit, vegetable and grain products, at the very time that FDA and the medical community are recommending greater consumption of these foods to prevent disease. There, thus, is no sound legal or public policy basis for EPA to continue its concentration and coordination policies, and EPA should not be permitted to perpetrate these policies to create an artificial pesticide crisis.

Although we believe that focused and reasonable legislation is the best way to reform the pesticide tolerance system, the administration's bill is clearly the wrong vehicle for this purpose. The Administration bill does little to improve the pesticide tolerance system, while incorporating numerous unnecessary and unjustified changes to FIFRA. Our specific objections to the Administration bill and reasons for favoring the Pryor-Lugar bill include the following:

OVERLY CONSERVATIVE AND RIGID FOOD SAFETY STANDARD

The Administration bill would impose an overly conservative and rigid safety standard for pesticide tolerances. The bill would require a separate safety standard for potential carcinogens, broadly defined to include any pesticide found to induce cancer in man or animals, or found to pose "a potential dietary risk of cancer in humans." The bill would specify the safety factors, uncertainty factors, and exposure assumptions that must be used in risk assessment, including the use of a tenfold safety factor and special risk factors for infants and children. This inflexibility in risk assessment methodology would generate exaggerated risk estimates and undermine the soundness of regulatory decisionmaking. It would inhibit the EPA's ability to exercise expert judgment, to take account of evolving scientific standards and to consider all relevant safety and exposure information. S. 1478, on the other hand, assures a science-based standard for pesticide tolerances and therefore represents the better approach to resolving the Delaney clause problem.

EXAGGERATED EXPOSURE ASSUMPTIONS

The Administration bill would require EPA to use worst-case exposure assumptions in tolerance determinations. EPA would be required to assume that food contains pesticide residues at full tolerance levels and that 100 percent of each crop is treated. Extensive data collected by FDA, USDA and the food industry over the past decade show that these assumptions are inaccurate, that pesticide residues in raw foods are far below tolerance levels and that residues in processed foods are often undetectable.

Under the Administration bill, actual crop treatment data could only be used in exposure assessments where a registrant could prove that no subpopulation group had higher exposure, and this determination would be subject to reevaluation at least every 5 years. This would effectively preclude use of realistic pesticide exposure data. The bill's artificial exposure assumptions would generate highly inflated risk estimates and would lead to unnecessary loss of many valuable pesticides, particularly for minor uses. By contrast, under S. 1478, EPA would be required, to the extent possible, to calculate dietary exposure on the basis of the percent of food actually treated with a pesticide, and on the basis of the actual residue levels detected in the food.

ESTABLISHMENT OF UNNECESSARY MULTIPLE TOLERANCES FOR A PESTICIDE ON A SINGLE FOOD

Under the administration's bill, EPA would be authorized to set multiple tolerances for a pesticide on a single food at different points in the distribution chain (*i.e.*, at harvest, at retail and after processing). In addition, the bill would authorize EPA to establish numerous separate tolerances for different processed forms of the same food. This would impose unnecessary additional registration burdens on pesticide companies and would create substantial enforcement difficulties for FDA. There is no need for a multiple tolerance system, and the public is likely to be confused by establishment of separate tolerances for a single pesticide on different forms of the same food.

Moreover, the Administration bill would require tolerances or exemptions for each pesticide chemical residue in food, including each substance that is present in food as a result of the metabolism or other degradation of a pesticide chemical. By contrast, S. 1478 would codify EPA's existing policy of considering pesticide metabolites and degradation products to be subject to the established tolerance for the precursor chemical, unless EPA has determined that the metabolite or degradation product is likely to pose different or greater health risks. The approach taken under S. 1478 would avoid the increased registration costs, administrative burdens and enforcement complexities of establishing multiple separate tolerances for metabolites and degradation products where there is no valid public health reason for doing so.

ELIMINATION OF BENEFITS CONSIDERATIONS IN TOLERANCE DECISIONS

The Administration bill would greatly limit the types of benefits that could be considered in pesticide tolerance decisions, would prohibit the continuation of a toler-

ance based on exceptional benefits beyond 5 years and would prohibit any consideration of benefits in tolerance decisions after 10 years. The bill would prohibit EPA from taking into account the value of a pesticide in maintaining an adequate, wholesome and economical food supply even though scientists and public health authorities now agree that adequate consumption of fruits and vegetables is a critical factor in disease prevention. Prohibition of consideration of benefits for pesticide tolerances would deprive growers of pesticides for which there are no alternatives, would undermine the health and welfare of consumers and would not achieve a meaningful risk reduction.

The Administration bill would permit consideration of benefits during a limited transitional period only where it could be proven that loss of a pesticide would cause "a significant disruption in domestic food production." This narrow standard would ignore substantial regional or seasonal disruptions and would effectively preclude benefits considerations.

The administration's proposal to eliminate benefits considerations in pesticide tolerance decisions is inconsistent with the basic registration standard under FIFRA and contravenes the fundamental policy set forth in section 1 of the administration's own Executive Order 12366, which directs Federal agencies to consider the costs and benefits of available regulatory alternatives and to adopt approaches that "maximize net benefits" to society.

DECOUPLING OF TOLERANCE REVIEWS FROM FIFRA REREGISTRATION

The Administration bill would require EPA, within 180 days of enactment, to review all existing pesticide tolerances and to identify each tolerance which does not appear to meet the requirements of the law. EPA would be required to call-in data and make a final determination with respect to most such tolerances within a 3-year period. This accelerated review provision is impractical, would conflict with the FIFRA reregistration process and would give EPA discretion to eliminate valuable food use pesticides without adequate procedural protections or a determination of unreasonable risk. Accelerated tolerances renewal would impose heavy burdens on EPA and pesticide registrants, and would create additional pressures for registrants to decline to support valuable food use pesticides. By contrast, S. 1478 would synchronize the schedule for reregistration and tolerance review decisions to ensure that EPA's tolerance decisionmaking benefits from the data being developed under the reregistration process.

NO TOLERANCE UNIFORMITY PROVISION

Under S. 1478, States and political subdivisions would be precluded from issuing different tolerance limits, warning requirements or other restrictions on pesticide residues in food, for pesticides registered or reregistered by EPA after April 25, 1985. This would secure EPA leadership in pesticide tolerance decisionmaking and would avoid the consumer confusion and substantial burdens on interstate commerce caused by special State requirements. Consumer protection would be assured by limiting required uniformity to pesticide tolerances supported by full scientific testing and recent EPA approval. States would be permitted to petition EPA for approval of a different tolerance on the basis of compelling local conditions. The Administration bill contains no national uniformity provision, thus inviting States to issue different and conflicting tolerance limits, which would undermine the Federal regulatory system.

NO INTERNATIONAL HARMONIZATION PROVISION

S. 1478 would require EPA, in establishing a pesticide tolerance, to take into account CODEX recommended international residue limits and to explain any departure from the CODEX limits. Setting United States tolerances consistent with established CODEX limits, where adequate safety data is available, would foster harmonization of international pesticide standards and would promote increased international trade in agricultural products. In spite of the administration's professed commitment to international harmonization, the Administration bill does not contain a comparable provision.

UNNECESSARY EXPANSION OF FDA ENFORCEMENT AUTHORITY

The Administration bill would grant FDA broad new enforcement power, including recall, embargo and civil penalty authority, with respect to pesticide tolerance violations for food products. FDA would be empowered to embargo food products for up to 30 days and to require immediate recall of food products on the basis of a "reason to believe" that the product is adulterated without any right to a

preenforcement hearing or review, and regardless of the magnitude of the alleged violation. Civil penalties of up to $250,000 per violation could be imposed against companies for any pesticide tolerance infraction, regardless of whether a potential health risk were involved. FDA already possesses ample enforcement power, including seizure, injunction and broad criminal penalty authority. There is no demonstrated need to grant FDA additional enforcement authority for pesticide tolerance violations.

ILL-CONSIDERED PHASE-OUT AUTHORITY

The Administration bill would grant EPA new authority to "restrict, reduce or eliminate" the use of a pesticide where "credible scientific evidence" indicates that use of the pesticide is reasonably likely to pose a significant risk to humans or the environment. This would empower EPA to limit or prohibit the use of a pesticide without the external scientific review and procedural protections guaranteed under the cancellation process, without any consideration of the pesticide's benefits, and on the basis of evidence that is too weak, incomplete or inconsistent to support a cancellation. Phase-out orders would generate damaging adverse publicity, disrupt sales of food products and cause irreparable harm to food producers and consumers.

Phase-out authority is unnecessary. Existing proposals to streamline the cancellation process would provide ample authority for prompt cancellation of pesticides that pose demonstrated risks and would assist in promoting consumer confidence in the food supply.

CITIZEN SUITS

The Administration bill would authorize any person to bring a lawsuit in Federal court against EPA, a pesticide registrant or any pesticide user, except for a farmer, for any alleged violation of FIFRA or of any EPA pesticide regulatory requirement. This provision would increase the litigation burdens of Federal courts, would interfere with EPA's enforcement prerogatives and would subject pesticide producers and users other than farmers to expensive and burdensome lawsuits.

WHISTLE BLOWER PROVISION

The Administration bill would give broad legal rights to any employee who alleges that he has been terminated, or that his employment status has been adversely affected, in retaliation for his bringing a legal action, or threatened legal action, for an alleged FIFRA violation. This provision would impair employer-employee relationships and impose further unnecessary burdens on employers and agricultural producers.

REVISED SUSPENSION PROCEDURE

The Administration bill would eliminate the current right of pesticide registrants for an expedited hearing on a proposed suspension order. EPA would be authorized to suspend a pesticide registration without a hearing for 180 days. If a cancellation proceeding was initiated within the 180 day period, the suspension would remain in effect until the completion of the cancellation process. This provision would give EPA excessive discretionary authority, would deny registrants a fair hearing and would cause irreparable harm to food producers who market products containing a suspended pesticide. Post-suspension court review, as provided for in the bill, would not offer a meaningful substitute for a presuspension hearing.

Proposed improvements to the cancellation procedure will give EPA sufficient power and flexibility to remove hazardous pesticides from the market in a timely manner. In true emergencies, EPA would retain its current authority to suspend a registration pending the conclusion of the expedited hearing.

By contrast, S. 1478 would retain existing suspension procedures, but would authorize EPA to issue an emergency suspension order before issuing a proposed cancellation notice. This would permit EPA to take prompt action against truly hazardous pesticides without the delay inherent in developing the full risk-benefit evaluation required for a cancellation notice. This provision, coupled with the 1988 FIFRA amendment which eliminated EPA's obligation to indemnify owners of existing stocks of suspended pesticides, would provide EPA sufficient authority to suspend registrations for pesticides that pose a true imminent hazard. EPA has shown no justification for granting the additional extraordinary suspension authority in the Administration bill.

BURDENSOME FEES

The Administration bill would require EPA to collect fees to cover the costs of administering the pesticide tolerance provisions of the Act, and would amend FIFRA to mandate additional reregistration and maintenance fees for food use pesticides. User fees of this kind unfairly penalize the regulated industry, undermine confidence in EPA's enforcement integrity and create additional disincentives for registrants to support valuable food use pesticides, particularly for minor crops.

We commend the subcommittee for opening a dialogue on pesticide reform and we stand ready to work with the Congress to develop food safety legislation that will give EPA the tools necessary to reach reasonable and scientifically defensible tolerance decisions. The Administration bill is not, in our view, the right vehicle for achieving this goal. We strongly believe that S. 1478 offers a reasonable, balanced and focused pesticide reform package, and we urge this committee to adopt S. 1478 as the model for crafting any legislation.

Jim Bender

Mr. Chairman, and Members of the subcommittee, I appreciate the opportunity to participate in this hearing. I am Jim Bender, an organic farmer from Weeping Water, Nebraska.

A central issue for pesticide policy concerns what American agriculture would be like with only minimal reliance upon chemical pesticides.

There are several ways to pursue this subject. An obvious one would be to study contemporary farms in which pesticides have been minimized or eliminated. Especially useful would be farms that are otherwise typical. By typical I mean farms that have developed with their fair share of agronomic challenges, do not rely upon inputs unavailable to agriculture in general, and have not received grants or other special funding.

Our farm comes to mind. It has been free of pesticides on all the land since 1980, and certified organic since 1990. It is a four generation family farm, 642 acres, located between Lincoln and Omaha at the very western edge of the nonirrigated corn-belt, which results in moisture extremes. Virtually all of the farm has been designated as potentially highly erodible by the Soil Conservation Service. The topsoil on many of the hillsides of the farm is thin as a result of profound soil erosion during the first decades of this century.

How does this farm perform? In many ways it is highly productive and conserving of resources. It competes with our chemical based neighbors in yields.[11] It is exceptionally resilient in years with difficult weather or economic conditions. We receive visitors and agricultural researchers each year who are complimentary about weed control. An aggressive, multifaceted soil conservation program coincides well with the pesticide-free cropping. It provides employment opportunities for local youth. Finally, while the farm has enjoyed special organic markets the last 2 years, prior to that mere conventional agricultural markets paid for land, large modern machinery, buildings, and other infrastructure.

The success of farms such as ours gives rise to a question. If these farms effectively address so many problems and offer other advantages, why then do our neighbors continue to farm in ways heavily reliant upon chemical pesticides? That is a question with no easy answer. A starting point, however, is the ways that Federal agricultural policy influences agricultural practice. There are many examples. Policy penalizes crop rotations that are essential no low and no-pesticide farming[12]; it generally does not orient research to support this kind of farming[13]. Federal Policy on highly erodible farm land places high priority upon pesticide based cropping practices[14]. Policy contributes to overly optimistic views of pesticide risk[15]. Current poli-

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[11] For additional data about yields and other performance indicators, see Bender, Jim. 1994. *Future Harvest,* University of Nebraska Press. Lincoln and London. p. 123–131.

[12] See National Research Council. 1993. *Soil and Water Quality*, National Academy Press, Washington DC. chapter 4. especially p. 153–6.

[13] See National Research Council. 1989. *Alternative Agriculture.* Washington, DC. National Academy Press. p. 6.

[14] See, for example, Schertz, D.L., Bushnell, J.L. 1993. "USDA Crop Residue Management Action Plan," *Journal of Soil And Water Conservation.* Volume 48. Number 3. May-June. pp. 175.

[15] An example of regulatory laxity which results in unfounded optimism is the Environmental Protection Agency's treatment of the issue of inert ingredients of pesticides. See, for example, General Accounting Office. 1986. *Pesticides: EPA's Formidable Task To Assess and Regulate: Their Risks.* GAO/RCED–86–125. Washington, DC., U.S. Government Printing Office. Chapter 5.

cies permit agricultural benefits to override health and safety concerns. These things and others influence agricultural practice.[16] They also begin to explain why farms such as ours are isolated, with so little influence.

In conclusion, there are currently low and no pesticide agricultural systems creating solutions to basic agricultural problems. Their effectiveness will continue to be limited until Congress removes existing obstacles.

Keith W. Eckel

The American Farm Bureau Federation appreciates the opportunity to address the issues raised by the administration's pesticide reform package and related proposals. Farm Bureau is the Nation's largest general farm organization, representing producers of all commodities in 50 States and Puerto Rico.

The concern over pesticide policy is intensifying due to several significant forces influencing the regulatory process. These forces include:

- Reregistration mandates created by the 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have forced safe and effective pesticides off the market, not for safety reasons, but for economic reasons. Pesticide losses are impacting growers throughout the country.
- The *Les* vs. *Reilly* Ninth Circuit Court of Appeals Decision forcing the Environmental Protection Agency (EPA) to enforce the zero tolerance Delaney clause could dramatically impact the availability of fruits and vegetables, especially if EPA implements its coordination policy.

Farm Bureau supports efforts to enact reasonable reforms to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act, (FFDCA). We believe the task of amending FIFRA and FFDCA should be done with clear purpose and intent of designing solutions to identified problems. The process simply is not able to sustain a "wish list" approach to reauthorization.

Several different pesticide proposals are currently pending before Congress. Farm Bureau supports the Pryor/Lugar bill, S. 1478, and H.R. 1627, by Representatives Lehman, Bliley and Rowland. This legislation has broad bipartisan support in both the Senate and the House, where it is now cosponsored by more than a majority of House Members.

The Federal Government has primary responsibility for safeguarding the food supply, but farmers are responsible for growing food safely. Growing and raising safe food is our top goal, and we are confident that new research breakthroughs and innovations will continue to yield a host of products and agricultural technologies that will help farmers provide an even safer, more healthful and affordable food supply. However, it is critical to remember that until research advances reach the farm gate, policies that arbitrarily reduce pesticide use will affect the supply and affordability of our food supply. These changes will affect low income Americans first, those who already consume 20 percent less fresh fruits and vegetables than people in higher income brackets.[17]

While a number of reforms to current law are needed, our pesticide policies are fundamentally protective of public health. Any reforms ought to be by design, intended to make a safe system safer and more efficient, not simply more bureaucratic. We share the views of former U.S. Surgeon General, Dr. C. Everett Koop when he said:

> *"I do not know of a single instance where exposure to pesticides on foods in the marketplace is a source of any danger to children or adults. It's a risk of zero."*

Dr. Bruce Ames of the University of California at Berkeley adds a word of caution to those who believe that tighter regulation will improve food safety:

> *"The attempt to prevent cancer by regulating low levels of synthetic chemicals by using worst-case, one-in-one-million-risk scenarios is not scientifically justified. It diverts resources from much more important risks. Perversely, it decreases consumption of foods that help to prevent cancer."*

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[16] For further elaboration upon the relationship between policy and agricultural practice, see "The Power of Policy," in National Research Council. 1989. p. 65–84. The Pesticide Food Safety Act of 1994 (H.R. 4091), introduced by Representative Henry Waxman, avoids this and other problems.

[17] Steven M. Lutz, David M. Smallwood, James R. Blaylock, Mary Y. Hama, Changes in Food Consumption and Expenditures in Low-Income American Households During the 1980's, USDA/ERS Human Nutrition Information Service, 1993.

THE GOAL OF LEGISLATION

The goal of legislation should be to design improvements to the current regulatory system. Several important areas should be addressed.

First, the primary objective of this effort should be to resolve the differences between FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA) as they relate to pesticide registration and the tolerance setting process. The "Delaney Paradox," as described by the National Academy of Sciences (NAS) in its 1987 report, stems from the contradictory regulation in the zero risk Delaney clause vs. the risk-benefit standard in FIFRA and section 408 of the FFDCA. The "paradox" in the law is that strict compliance to the Delaney clause prevents newer, safer but minutely carcinogenic pesticides from reaching farms to replace older, riskier pesticides. Continued adherence to a "zero risk" public policy is neither scientifically credible nor achievable. Coordinating efforts in FIFRA and FFDCA through a negligible risk standard is an essential component for pesticide reform.

Second, legislative reform should create a single regulatory standard applicable for both fresh and processed foods.

Third, there is general consensus that the process for removing pesticides determined to present an unreasonable risk to health or the environment takes too long and should be expedited.

Fourth, it is essential that newer, safer products and technologies be developed and approved more quickly to replace those being lost. The lack of replacement products is the most frequently voiced concern by farmers when discussing pesticide policy.

Fifth, the loss of pesticides for "minor uses" is acute and needs to be resolved. Separate legislation, sponsored by Senators Inouye and Lugar, would alleviate this concern. The problem is time-sensitive and needs to be addressed in this Congress.

Sixth, is the need to retain the risk-benefit consideration in the registration and tolerance setting process. The most compelling description of the benefits from pesticide use was given by Nobel laureate Norman Borlaug:

> ". . . [I]f U.S. farmers used the agricultural technology of the 1930's and 1940's to produce the harvest of 1985, they would have to convert 75 percent of the permanent pasture lands in the United States or 60 percent of the American forests and woodland areas to cropland. Even this may be an underestimation, since the pasture and forestlands are potentially less productive than the land now planted to crops. This would greatly accelerate soil erosion and destroy wildlife habitats and recreational areas."

The benefits of pesticides accrue to all of society, not just to farmers, and their consideration in pesticide regulatory decisions is critical for a reasoned and coordinated policy. The benefits of pesticide use must be balanced with risks along with the need to feed a world population that is growing by nearly 100 million people every year.

REDUCING PESTICIDE USE

According to National Agricultural Statistics Service surveys, total pesticide use has trended downward since 1982. (Appendix 1)[18] This is an important factor that should be considered when setting policy. Farmers have adopted new technologies that have resulted in tremendous efficiencies over the last decade. Further efficiencies will come through new technologies and public policies that encourage, rather than impede their development and use. We are troubled by what appears to be a prevailing attitude so heavily weighted toward the removal of products, rather than the introduction of newer, safer replacements. We continue to support innovation in farm practices that will reduce pesticide use. Some of the ideas and options that Farm Bureau has advocated during the past several years that will reduce total pesticide use include research to find alternative pest control products such as biological control agents, microbial pesticides, resistance management including the use of genetic engineering, growth regulators and breeding for host plant resistance. We also believe that improvements in pesticide application technology and improved applicator training in reduced use methods will also substantially decrease the need for pesticides without burdensome new regulations aimed at limiting a farmer's control options.

Dollars are needed to fund this type of effort, and the administration's package does not specify the dollar commitment its intend to seek as part of its use reduction

[18] USDA/ERS Report #622 and USDA/NASS reports "Agricultural Chemical Usage, Field Crops Summary" for 1990, 1991, 1992 and 1993.

strategy. The need for research dollars for alternatives to pesticides must be the beginning portion of any strategy that has as its goal substantial reductions in pesticide use.

The lack of new moneys for research on pesticide reduction projects is critical. Right now, the American Farm Bureau Research Foundation is reviewing eight new research projects totaling $370,000 that will develop information that farmers can use to reduce pesticide use. One project is to examine biological control for cotton insect pests in Texas. We can finance only a fraction of the research projects that come through our foundation. The National Coalition for IPM estimates that the total dollar commitment to achieve meaningful results so that farmers can further reduce pesticide use is $50 million per year for the next 5 years.

Already much is being done. In April, at the National Symposium for Integrated Pest Management, over 200 research projects highlighted the vast array of new ideas that will help farmers reduce total pesticide use. We have long been an advocate of IPM and of reducing the many constraints to broader utilization of this pest management philosophy. For the record, I would like to submit and call your attention to two items. First is a report prepared by Dr. Michael Fernandez of the Senate Agriculture Committee staff summarizing some of the many successes attributable to IPM. Second, a report from last year by the National Foundation for Integrated Pest Management exploring the many constraints which hamper greater utilization of IPM. This information was gathered through a series of regional producer workshops. We need to build upon the vast and impressive research network throughout the land-grant university system to develop sound production and management practices that will enable farmers to minimize pesticide use.

Farm Bureau policy for minimizing pesticide use is clear and supportive of the following:

1. The widespread promotion and use of integrated pest management (IPM) as a method of reducing costs, risks, liability and total dependence on farm chemicals. Expanded educational and pesticide training certification programs should encourage the adoption of IPM.

2. Continued research and development of pesticides which degrade more rapidly, are less environmentally persistent and are compatible with accepted IPM practices.

3. Increased biological pest control research to determine where biological pest control measures can provide practical and feasible substitutes for nonbiological pesticides.

4. A beneficial insects category in USDA's competitive grants program.

5. Improved training programs on the proper handling and safe use of pesticides to ensure the safety of handlers, applicators and agricultural workers.

6. A well funded IR–4 program. Funding for the IR–4 program has crept up, but it is still far short of the $14 million needed to remove the backlog of outstanding requests.

7. Continued research on the effects of farm chemicals on the environment. Congress can also create incentives for farmers to reduce pesticide use and to find safer alternatives. Incentives could include:

- Streamlining the EPA registration priorities for EPA. Right now EPA has registration priorities for pesticides that replace section 18's, for "safer" pesticides, for pesticides that reduce use, for pesticides used on minor crops and for biological pesticides. Because EPA has so many registration priorities, nothing becomes a real priority. We suggest EPA focus in on the areas where farmers' control options are most limited and where risk is highest without classifying registration priorities by pesticide type.
- EPA should work to harmonize State/Federal/international research and development incentives for pesticide registrants.

Farmers will continue to reduce pesticide use by achieving greater efficiencies from the adoption of new technologies and information transfers. The administration has taken some positive steps toward meeting some of our goals, but more is needed. A greater focus is needed on increasing the number of product registrations approved for use. The loss of key products without approved replacements is jeopardizing much of the progress we have made. Farmers have shown that when proven new technologies become available, they will adopt them.

BUILDING UPON OUR CURRENT FOOD SAFETY SYSTEM

The central question to the pesticide debate is "How can our current food safety system be improved, without undermining what is generally viewed as successful

in producing the safest and most abundant food supply in the world?" This is also the question Congress must answer if it expects to resolve the gridlock. Our perspective is clear. While our current system needs improvement, the evidence is overwhelmingly in favor of building upon what we have, rather than making drastic changes.

There is a lot of good news for the American food consumer: the supply of food is safe and bountiful, quality is unparalleled, variety is ever-expanding and prices are reasonable. The American farmer/government/university food production system is unrivaled. The quality of life and health provides sufficient evidence and argument to build upon our current system.

It is important to note that while modern technology has greatly improved our ability to measure or detect the tiniest trace of chemicals in food, we have had no increase in our ability to make these numbers useful or meaningful to the food policy process. This results in periodic food safety scares. They do not mean that our current system needs an overhaul. Residue testing is a good example.

In May 1991, the U.S. Department of Agriculture implemented the Pesticide Data Program (PDP) to collect objective, comprehensive data on pesticides in fresh fruits and vegetables. In April, results from 1992 were released.[19] In 1992, the PDP analyzed 5,750 fruit and vegetable samples and found that 61.2 percent of the samples contained detectable residues.

At first glance, this may seem high, but closer examination reveals otherwise. Only 63 of 5,750 samples contained residues in violation of the tolerance. Keep in mind that the tolerance is the safe and legal limit of the amount of pesticide residue that may be present in raw or processed foods. Fifteen of those 63 samples with illegal residues were from imported food. Fifty-three examples had residues where no tolerance was established by the EPA. Only 10 samples contained residues in excess of the established tolerance.

The PDP also compared detected residues with the pesticide tolerance for 40 pesticide/commodity pairs. Of those pairs, only five pairs resulted in a mean concentration which exceeded 10 percent of the tolerance, with the highest value representing just 22.5 percent of the established tolerance. In other words, a minimum tenfold safety margin could be added to the tolerance for 35 of the pesticide/commodity pairs and the mean detection would be under the established tolerance. For some pesticide/commodity pairs, the safety margin could be increased by as much as 200 times and residues would still be under tolerance. Regrettably, some groups have used our increasing ability to detect as a means to generate interest among the media and fear among the public.

This data indicates that our current food safety system works and changes need to build upon what is already a solid foundation.

In reviewing the many issues addressed in the pending legislation, we are troubled by much of what is in the administration proposal. We believe that there is a need for reasoned, careful reforms in both FIFRA and FFDCA. We do not believe the administration's proposal accomplishes the challenge of improving our current system. Rather, it proposes a number of new authorities and changes to FIFRA and FFDCA that are simply unjustified. The challenge is to improve the regulatory system, not merely to make it more difficult to navigate.

Our specific concerns with the administration proposal include the following.

Loss of Benefits Consideration in the Registration and Tolerance Setting Process. The administration proposal will not allow the consideration of benefits of a pesticide in excess of the risk standard, and will eventually phaseout benefits consideration altogether. A risk-only approach to pesticide regulation does not reflect the contribution of pesticides to our food supply. It is important to note the benefits society derives from the safe and judicious use of crop protection chemicals. Among them:

- Agricultural chemicals reduce the risks of crop failure and stabilize food production. Farm Bureau has catalogued a list of crops affected by the loss of minor use pesticides to demonstrate the role pesticides play in food production. "The Loss of Safe Pesticides for Minor Crops" cites examples from 32 States, and we have provided the subcommittee with copies of the report. We have also submitted research from Texas A&M University entitled "*The Economic Im-*

[19] Pesticide Data Program (PDP), Summary of 1992 Data, U.S. Department of Agriculture, Agricultural Marketing Service, 1994.

pacts of Reduced Pesticide Use on Fruits and Vegetables" [20] as further evidence of the benefits derived from pesticide use.

- Agricultural chemicals allow food to be produced on less land. Land that would otherwise be needed for food production can be devoted to wildlife habitat and other beneficial uses. Pesticides also allow environmentally fragile lands to be idled. Fewer farmed acres reduce the amount of water needed for irrigation.
- Agricultural chemicals allow the use of soil conserving practices that reduce the soil erosion that results from increased cultivation to control weeds.
- Agricultural chemicals reduce farm costs. Reduced costs allow us to compete in world markets. Lower farm costs also translate to lower food costs which encourage consumption of foods important to health. There is a growing body of evidence that greater consumption of fruits and vegetables help prevent cancer. Higher food costs are likely to limit the production of foods we should be consuming most. In 1988, the *Surgeon General's Report on Nutrition and Health* said this:

  "Some epidemiologic evidence suggests that frequent consumption of vegetables and fruits, particularly dark green and deep yellow vegetables and cruciferous vegetables, may lower risk for cancers of the lung and bladder as well as some cancers of the alimentary tract."

- Agricultural chemicals allow food to be grown domestically, rather than depending on imports where we have little to no control over food production methods.
- Agricultural chemicals improve the quality and storability of food. Consumers can expect more perishability at the marketplace as a result of pest infestation and consumer rejection of products with poor appearance and quality if farmers are forced to arbitrarily reduce pesticide use. Consumers can expect poorer quality of foods that are typically stored for long periods, like apples. High quality foods are essential for meeting export standards as well. Customer countries will restrict United States products if they do not meet quality or phytosanitary standards.
- Agricultural chemicals have substantially decreased farm labor requirements, as well as associated costs.

The Clinton plan would not permit approval of any pesticide tolerance with a greater than one-in-one million lifetime cancer risk, regardless of benefits. Ignoring the benefits of crop protection chemicals in the registration process presumes that a widely available and affordable food supply plays no role in human health. In choosing to eliminate benefits consideration, EPA has failed to make its case. Why after three decades is this change of course warranted? Where is the evidence supporting this? What measurable gain in food safety will be seen from this? Farm Bureau supports the consideration of both the risks and the benefits of pesticides in the evaluation of chemical products and cannot support the administration's proposal.

Negligible Risk. The administration's proposal defines negligible risk as a one-in-one million cancer risk over a lifetime using 100 fold safety factors. This rigid safety standard is an inflexible standard that cannot be changed with improvements in science and technology. In some cases, the new standard may be worse than the Delaney clause due to its inflexibility.

It is impossible for Farm Bureau to predict the impact and loss of current registrations if EPA were forced to implement the new standard. We urge the subcommittee to ask EPA to analyze the outcome to current tolerances and registrations and ultimately, the impact on food production under the proposed negligible risk standard.

Farm Bureau supports a flexible negligible risk standard. One of the primary lessons from Delaney is that rigid standards do not adapt to changing science. A flexible risk standard recognizes that risk assessment is constantly evolving and improving. A flexible standard that allows the EPA to update its methodology to keep pace with the developing science of risk assessment is an essential part of a coherent food safety policy.

Tolerance Uniformity. The administration's plan has no provision for tolerance uniformity. States would not be prohibited from setting pesticide tolerances that are more restrictive than Federal standards. Farm Bureau supports provisions that prohibit States from establishing pesticide tolerances that are more stringent than Federal tolerances, unless very special local conditions warrant consideration for a more restrictive tolerance.

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[20] Ronald D. Knutson, Charles R. Hall, Edward G. Smith, Samuel D. Cotner, John W. Miller, Economic Impacts of Reduced Pesticide Use on Fruits and Vegetables, 1993.

Exposure Analysis. Farm Bureau supports the use of actual pesticide use data in exposure analysis, wherever possible. We strongly disagree with the administration over its intention to use exaggerated exposure assumptions, such as 100 percent of crop treated at full label rate and minimum preharvest intervals. We question the purpose of the data collection provisions if worst-case assumptions are mandated anyway. As written, this provision will result in the continuation of overstated and unrealistic risk estimates.

Phase-Out/Phase-Down. Farm Bureau disagrees with the administration's plan that would allow EPA, without a complete scientific review, to phase-out/phase-down a pesticide by imposing production caps or eliminating uses. This new authority is extremely vague and loose. This is seemingly a "catch-all" provision that provides the Agency with new authority for arbitrary action. From the perspective of a farmer, this provision would add even more uncertainty and risk to our farm management decisions. We believe it would also hinder the mutual goal of greater adoption of integrated pest management and other similar strategies. It is unclear what situations this is intended to address and why existing or proposed expedited cancellation and suspension authority are inadequate.

Enforcement Provisions. The administration proposal spells out a broad new set of enforcement guidelines, including requiring all private applicators to keep records of all pesticides they use, both general and restricted use.

Farmers will be required to notify EPA where records are maintained and will be required to furnish EPA a copy of the records on written request. Any employee of the United States or States who has been designated by the EPA will have the authority "to enter and inspect" to obtain: a) Samples of any pesticide; b) Copies of any records or of any pesticide labels; c) Copies of documents related to compliance under the Act; d) Copies of any data or samples of any specimens involved in the testing of any pesticide; and e) Samples of any places where pesticide residues may be found, including, without limitation, agricultural commodities, animals, pests, soil, or water.

Equally troubling is the elimination of the first offense warning to farmers now required in current law. The overwhelming volume of regulations under FIFRA makes it essential that farmers be given a notice and warning of a violation in the first instance.

We are also troubled by the substantial increase in civil and criminal penalties to registrants, commercial applicators and dealers, especially the smaller family businesses. Particularly threatening is that the standard for any FIFRA violation has been changed from a "knowing violation" to a mere act of negligence. This will surely affect many small, family owned dealerships and commercial applicators throughout rural America, and also the ability of farmers to obtain the tools, information and services they need.

The administration's enforcement provisions are excessive and unjustified. There has been no demonstrated need for such drastic changes in policy.

Whistleblower Provision. The Administration bill proposes to establish broader authority and rights to any employee who alleges wrongful termination of employment, or that the employee's status has been adversely affected in retaliation for bringing, or threatening to bring, a legal action alleging a violation of FIFRA.

Again, there has been no documented need or justification for such sweeping new authority in FIFRA. It will add substantial new risk for farmers and impair employee/employer relationships.

Citizen Suits. Farm Bureau opposes provisions in the administration's plan that provides an opportunity for citizens to ask the EPA "to commence an action against any agricultural producer who is alleged to have violated . . . any provision of the Act." Enforcement by citizen action implies that the Government is incapable of enforcing the law by itself and needs help from citizens to uphold the law. Citizens are not trained or qualified to properly enforce or even report on suspected violations of Federal pesticide law and is a provision that Farm Bureau strongly opposes. If Congress sees fit to create Federal laws that the Government cannot enforce, then certainly citizen action is not the answer. Allowing citizen action against farmers is unnecessary, punitive and forces farmers to defend themselves against alleged violations that will be prosecuted by the Federal Government.

Pesticide Cancellation. We support changes in FIFRA, outlined in S. 1478, that will streamline the process for cancellation of potentially dangerous pesticides. The existing cancellation process is lengthy and hampers EPA's ability to remove potentially dangerous pesticides from the market in a timely manner. The cancellation process should move quickly if a full and complete analysis of the data supports the cancellation of specific pesticide products. However, in fairness to both the registrant who has invested millions of dollars in research and development, and

farmers who depend on the availability of these tools, the cancellation process should continue to include adjudicatory hearings and the opportunity to present evidence and to cross examine. Farmers rely on the registration process for safe, effective pest control products. If new evidence supports the cancellation of products, that process should move quickly. Much of the integrity of pesticide registration relies on the ability to deal quickly with products determined to pose unreasonable risks.

Suspension. The administration's bill would eliminate the right of a registrant to an expedited hearing on a proposed suspension order. EPA would be authorized to suspend a pesticide registration for 180 days without a hearing and without requiring a notice of intent to cancel. This provision would deny registrants a fair expedited hearing and would create unnecessary confusion and uncertainty for farmers who market products containing a suspended pesticide. For these reasons Farm Bureau opposes the bill's suspension provisions.

Label Call-In. We support the concept of a label call-in program as long as this authority extends only to minor label changes. Label call-in should not remove crop uses or substantively alter the use of the product. While a label call-in program might be one area where agreement could be forged, the current language of the Administration bill is much too broad and gives EPA virtually unlimited authority to make changes.

Integrated Pest Management. Last September, the administration set a goal of implementing IPM programs on 75 percent of crop acreage by the year 2000, but the new bill properly sets no such numerical goal. To accomplish the IPM goals, the administration proposes to require pesticide training and certification programs to include instruction in integrated pest management techniques. Pesticides critical for IPM programs, but which may pose higher risks, may be available for prescription uses. Such changes are encouraging but must be accompanied by an on-going commitment to overcome numerous impediments. Farm Bureau is fully committed to working with the Agency on this.

We are concerned that the bill does not identify any specific actions or Federal funds to develop research and new technologies that will allow farmers to achieve wider adoption of IPM. We strongly encourage that additional Federal research moneys be appropriated for IPM research and technology transfers.

Farm Bureau has been a strong proponent of efforts to expand the utilization of integrated pest management. We applaud the administration for their work in this area.

Pesticide Use Data Collection. The administration plans to collect additional pesticide use data to improve pesticide regulatory decisions. Farm Bureau supports the collection of actual residue data from farm products to establish use patterns for pesticides. This data should be used in the pesticide registration, reregistration, cancellation and special review process only. We cannot support the administration's mandatory record keeping proposal for all pesticides, due in large part to its punitive nature that includes inspections of records by Federal employees and others. We also find it inconsistent that the legislation emphasizes data collection, yet fails to allow, for practical purpose, the use of that data in determining exposure assumptions.

Minor Use Pesticides. Farm Bureau is a member of the Minor Crop Farmer Alliance and strongly supports the "Minor Crop Pesticides Act of 1993," (S. 985 and H.R. 967) introduced by Senator Inouye and Representative de la Garza. The administration recognizes the minor use problem and has incorporated some provisions similar to the reforms advocated by the Inouye/de la Garza proposal. While generally positive and consistent with those of S. 985/H.R. 967, we believe they need to be strengthened in order to achieve the intended solutions so desperately needed. Under their plan, exclusive data use will be extended for 2 years instead of 10. IR–4 funding will be expanded. Transitional registrations will continue until reregistration is complete for specific pesticides. These reforms move toward our objective. Farm Bureau encourages the committee to act on this very time-sensitive problem this year. A copy of the Minor Crop Farm Alliance statement has been submitted for the record.

Reduced Risk Pesticides. We support the effort to establish guidelines for reduced risk pesticides. We also support provisions that create incentives for registrants to develop safer pesticides so farmers can use them once they are registered. We are concerned about the potential for creating a stigma on products that may not meet subsequent guidelines to qualify as "reduced risk" but nonetheless are safe and lawfully registered for use. Furthermore, we would urge caution and consideration over the potential for such a designation to be misused by retailers or food processors

in dictating which products should be used. The objective of a reduced use policy should be to expedite the approval process for those products that meet such guidelines.We support the administration's plan to give registration applications that meet the new criteria priority and expedited review and thus also qualify for exclusive data use. We also support conditional registrations for biologically based pesticides before a full data set is developed.

Conclusion

The concern over pesticide policy is a concern that farmers share. But our view is tempered by two fundamental considerations.

First is the knowledge that agricultural chemicals and bio-pesticides will remain essential tools to control pests for the foreseeable future. They will continue to be needed to protect our food supply from insect, disease and weed pests.

Second, our public laws governing pesticide policy are fundamentally sound and protective of public health and the environment. While it is always prudent to seek refinements where known problems exist, it should be done with a clear purpose, intent and design. There is not a need for drastic reform, rather changes should be reasoned and deliberate. Your approach should be laser-like in its focus.

The Administration bill proposes a major overhaul of FIFRA with virtually no justification for many of the proposed changes. Among the changes are the elimination of benefits consideration, limits on public participation rights, new arbitrary authority to phaseout pesticides, and the establishment of new enforcement authorities, such as citizen suits and the elimination of the first offense warning to farmers. Many of these proposals are excessive and punitive in their design.

In contrast, the need to replace the Delaney clause with a single, flexible standard of negligible risk is clear and widely acknowledged. However, the administration has proposed a similarly rigid and arbitrary safety standard to replace it. It further proposes to reevaluate tolerances on a schedule that is inconsistent with the reregistration schedule required by this Committee in the 1988 FIFRA amendments. This makes no sense and will serve only to increase the costs and pressures against manufacturing a product. The effect will be to accelerate the rapidly declining number of pesticide options currently available to farmers. This proposal goes well beyond the reforms to the tolerance setting process recommended by the National Academy of Sciences in its 1987 report *Regulating Pesticides in Food.*

EPA has chosen to place the burden and responsibility for action squarely on Congress, to avoid the potentially harsh effects of a strict policy application of the Delaney clause stemming from the Ninth Circuit Court Decision in *Les.* v. *Reilly.* While we agree that clearly targeted and reasonable legislation is the best way to address these issues, the Agency has chosen to ignore other nonlegislative remedies that could avoid or soften the impact on farmers and consumers. In fact, it has taken every action to increase the potentially harsh economic impact upon the farm community in order to create pressure on Congress to reform the law. We believe this to be a particularly unnecessary and irresponsible action with unknown consequences to agricultural producers.

The impacts of *Les* vs. *Reilly* case and the Delaney clause should and can be avoided. Neither farmers nor consumers will benefit from the "train-wreck" approach to policy that is currently being pursued.

Thank you for the opportunity to comment.

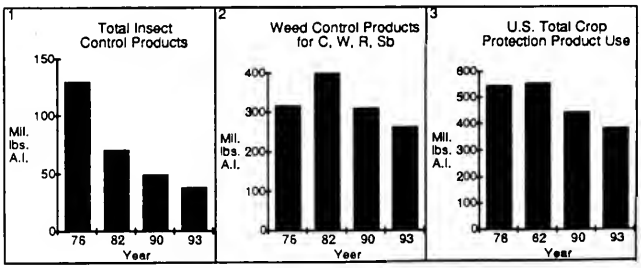
U.S. Agricultural Crop Protection Product Use From 1964 to 1993 On Major Crops

Year	1964	1966	1971	1976	1982	1990	1991	1992	1993
				Million Pounds Active Ingredient					
HERBICIDES									
Corn	25.5	46.0	101.1	207.1	243.4	217.2	189.10	199.10	181.90
Wheat	9.2	8.3	11.8	21.9	18.1	11.8	9.90	12.50	14.20
Rice	na	2.8	8.0	8.5	14.1	9.7	10.40	11.30	11.30 *
Soybeans	4.2	10.4	36.5	81.1	127.0	74.3	63.10	58.80	57.10
Subtotal	38.9	67.5	157.2	318.6	402.6	313.0	272.50	281.50	264.50
Other Herbicides	31.6	33.7	55.9	55.3	53.0	53.0 *	53.00 *	53.00 *	53.00 *
Total Herbicides	70.5	101.2	213.1	373.9	455.8	366.0	325.50	334.50	317.50
INSECTICIDES									
Corn	15.7	23.6	25.5	32.0	30.1	23.3	20.90	18.40	16.60
Wheat	na	0.9	1.7	7.2	2.6	0.0 **	0.15	0.90	0.12
Rice	na	0.3	1.0	0.5	0.6	0.1	0.15	0.09	0.09 *
Soybeans	5.0	3.2	5.8	7.9	11.1	0.0 **	0.37	0.13	0.31
Subtotal	20.7	28.0	33.8	47.6	44.4	23.4	21.58	19.52	17.12
Cotton Insecticides	78.0	64.9	73.4	64.1	16.9	16.9 *	6.30	11.00	11.90
Other Insecticides	18.0	15.3	20.7	18.6	9.9	9.9 *	9.90 *	9.90 *	9.90 *
Total Insecticides	116.7	108.2	127.9	130.3	71.2	50.2	37.78	40.42	38.92
ALL FUNGICIDES	5.8	8.0	6.4	8.1	8.6	8.6 *	6.60 *	6.60 *	6.60 *
ALL OTHER PESTICIDE	31.7	35.7	29.8	35.3	24.3	24.3 *	24.30 *	24.30 *	24.30 *
U.S. TOTAL	224.7	251.1	377.2	647.8	557.7	447.1	394.18	405.82	387.32

* Assumed to stay the same as in previous year because full data was not available for indicated year.

** Some insecticides were used, but no amounts were reported by the National Agricultural Statistics Service because those insecticides were used on less than one percent of the acres planted.

Sources: USDA ERS Report #622 and USDA/NASS reports "Agricultural Chemical Usage, Field Crops Summary" for 1990, 1991, 1992, & 1993. pl\pesttren



Compiled by Public Policy Division, American Farm Bureau Federation, April, 1994

Ralph Engel

My name is Ralph Engel. I am president of the Chemical Specialties Manufactures Association (CSMA) located at 1913 Eye Street, Northwest, Washington, DC.

CSMA has membership of some 440 firms engaged in the manufacture, formulation, distribution and sale of pesticides, antimicrobial products, automotive chemicals, detergents and cleaning compounds and polishes and floor finishes for household, institutional and industrial use. A significant number of these products have pesticidal claims and are therefore subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Specifically, CSMA represents the nonagricultural pesticide industry, including disinfectants and sanitizers, home, lawn and garden pesticides and a wide variety of pesticides for home, industrial and institutional use. Our testimony today focuses on three areas: The Clinton Proposal, antimicrobial products and other issues affecting the pesticide registration process.

THE CLINTON PROPOSAL

Mr. Chairman, at the outset I want to note that the Clinton administration has expended considerable effort in assembling a comprehensive FIFRA and Federal Food, Drug and Cosmetic Act (FFDCA) reform package. There are difficult public policy questions addressed in this package and the administration's willingness to engage these issues is to be recognized.

Having said that, the chemical specialties industry cannot support the Clinton legislation and feels that it is not the balanced Middle of the road" proposal that its proponents would have you believe.

We wish to note that over the past few years, the Environmental Protection Agency (EPA) has expressed concern over what it considers to be the cumbersome and time-consuming process required to cancel or suspend a registration. CSMA understands the Agency's concern and believes it must be provided the tools to promptly address pesticides which pose an unreasonable adverse effect to human health or the environment. We also believe that the continued safeguards afforded through administrative adjudicatory hearings are in fact absolutely necessary and proper. This process ensures an adequate chance for rebuttal by the registrants as well as a proper forum for consideration of all relevant factors for cancellation or suspension of a pesticide.

CSMA will continue to objectively look at any reasonable proposal proffered by EPA and others concerning this issue but remains committed to maintaining appropriate procedural safeguards. Unfortunately, many of the provisions in the Clinton Package attempt to circumvent administrative protections. Accordingly, we in the chemical specialties industry have very serious concerns with the legislation. Among these concerns are:

Elimination of Benefits Considerations. The administration has essentially proposed the phase-out and elimination of benefits considerations in registration, suspension, and cancellation decisions over a period of 10 years. FIFRA is the last major environmental statute which provides for a risk-benefit standard. Flexible consideration of benefits in these decisions is consistent with the FIFRA's societal risk-benefit requirements and is essential to preserving EPA's ability to take into account the value of a pesticide in determining whether or not to register the product or to let stand an existing registration.

In fact, an analysis of benefits of such products as antimicrobial which provide public health benefits is a legitimate and important consideration which must be preserved in the regulatory process. Antimicrobial pesticides (disinfectants, sterilants, industrial biocides) account for approximately 30 percent of all active ingredients and products registered under FIFRA. These pesticides provide substantial public health benefits by preventing or destroying bacteria, fungi, viruses and other dangerous microorganisms (legionella, salmonella, etc.). Preserving the consideration of those health benefits is absolutely critical to the public health and to this industry. Dropping this factor from the regulatory process would be a disservice to the public and would actually weaken protections for the public presently afforded under FIFRA.

The administration's proposed elimination of benefits considerations is inconsistent with the fundamental goals of its own Executive Orders 12866 on Regulatory Reform which directs Federal agencies to consider the costs and benefits of available regulatory choices and to select approaches that "maximize net benefits" to society. Specifically, Executive Order 12866 signed by President Clinton on September 30, 1993, requires any agency developing a regulation to: 1) assess both the cost and benefits of the intended regulation and proposed and adopt it only if its benefits justify its costs, 2) base its decisions on the best reasonable scientific, technical, and

economic information, 3) identify and assess alternative forms of regulation, 4) avoid duplicative regulations, and 5) tailor it regulations to be the least burdensome on society. We submit that elimination of benefits considerations clearly violates this Order and on this basis alone should not be included in any FIFRA legislative package.

Rigid Negligible Risk Standard. The narrative standard "reasonable certainty of no harm" as advocated by EPA is actually severely restricted by a statutorily prescribed numerical margin of safety ($1x10^{-6}$) and very conservative exposure assumptions, particularly for children and infants. CSMA would continue to support a narrative definition of "negligible risk" consistent with present risk ranges ($1x10^{-5}$ to $1x10^{-6}$) used by EPA, FDA, and other Federal agencies. The risk assessment process, for cancer and noncancer risks, should not be prescribed in statute; it should instead provide EPA with appropriate scientific flexibility and discretion.

Phase-Down/Phase-Out. The administration proposal gives EPA authority to "restrict, reduce, or eliminate" the use of a pesticide where "credible scientific evidence indicates that the use of the pesticide is reasonably likely to pose a significant risk to humans or the environment." This authority would accelerate the extinction of the FIFRA cancellation process by encouraging EPA to limit or ban the use of a pesticide based upon a diminished scientific threshold.

The proposed standard itself is overly broad and would result in a reduction in the use of appropriate scientific standards to make regulatory decisions. Moreover, data upon which the decision would be based would not have undergone outside scientific peer review. The due process protections under FIFRA's cancellation process would be eliminated. Phase-out/Phase-down actions would severely damage the affected consumer products with adverse publicity, from which it would be difficult to recover even if it were later determined that the Agency was in error. Such actions would be grossly unfair and are not needed in view of current protections which mandate that regulatory actions be predicated on good science.

Fees. One year ago, EPA testified that it needed $20 million through 1997 in new fees to complete its FIFRA 1988 reregistration mandates. Today, the administration outlined its revised fees proposal which now calls for more than $60 million through 1999 in three categories (maintenance fee extension, a $750 per product registration fee, and new active ingredient reregistration fees).

Let me simply emphasize that this subcommittee and the Congress should withhold assessing any additional fees on registrants, or granting any additional fee authority to EPA pending a thorough review of the registration and reregistration programs. Such a review should include an examination of the funds collected and utilized in both programs thus far and a specific documented accounting of the use of fees collected in previous years.

EPA Assistant Administrator Goldman's recent decision to contract with an outside management consultant to give her an operational assessment of Office of Prevention, Pesticides and Toxic Substances (OPPTS) is a courageous and valuable step in the right direction. That outside management review must contain a serious financial audit component. We look forward to working with EPA and the management consultants on this, and related issues.

Reduced Risk Pesticides. CSMA and the chemical specialties industry support the goal of encouraging the development and production of pesticides presenting lower risks than those presently on the market. We believe, however, that if the registration process itself were functioning properly, much of EPA's "safer pesticides policy" would not be needed.

Frankly, we fail to understand why EPA is posturing itself to take on the creation of yet another manpower intensive project to catapult, perhaps wrongfully, some applications for registrations of pesticide actives and products ahead of others (risking litigation in the process) when the competitive market place would accomplish this very same goal if the Agency would streamline the unnecessarily burdensome and often nonfunctioning registration program. For example, in the antimicrobial sector—with generally low risk/low exposure pesticides being used *indoors*—only *eight* active ingredients have been registered in the past 10 years (6.5 percent of the 127 new active ingredients registered in the last 10 years).

Faced with virtually no prospect of attaining registration in a useable timeframe, companies have significantly restricted research and development activity on new antimicrobials. These delays hinder market introduction of new antimicrobial active ingredients and products posing even lower risks and providing greater efficacy than those chemicals presently in use. Similar problems with the registration process in other segments of the pesticide industry have also reduced research in new chemicals and have stymied the competitive marketplace.

Finally, the Clinton bill authorizes a cooperative agreement program under which the Federal Government would make grants to private groups, institutions, and individuals pursing reduced pesticide use. The establishment, at this time, of a new Federal grant program for this purpose, seems at best out of place given the internal problems with Office of Pesticide Program's (OPP's) registration system which demand attention.

Label Call-In. The administration proposes a new Label Call-In Authority which would allow EPA through a simple notice procedure to require changes in the "labeling, packaging, or composition of the pesticide." The threshold to be met by the Administrator before taking such action is minimal; The Administrator need only determine that "the risks associated with the use of a pesticide can be reduced." In case of noncompliance, suspension without hearing is authorized and recalls and compensation can be ordered by the Agency.

Since pesticide use of any kind will generally involve some level of risk, this provision would grant the Administrator broad authority to delete or restrict pesticide use which EPA has explicitly previously approved as being within an acceptable negligible risk range.

The Agency would be under no obligation to demonstrate an "imminent hazard" or even an adverse effect on man or the environment but merely that risks can be reduced. The Label Call-In procedure outlined in the bill affords the registrant scant due process protections. This provision is thus a further method to reduce due process and fairness in the regulatory process and must therefore be rejected.

Export Restrictions. CSMA supports a ban on the export of pesticides which have been suspended or canceled due to human health concerns. The Clinton bill appears to include nonfood use pesticides in its "Circle of Poison" provision, allowing only for an exemption by the EPA Administrator on a case-by-case basis. This is inefficient and unnecessary to address the stated issue of concern—that is dietary exposure from pesticide residue in or on imported foods. nonfood use pesticides should be specifically exempt from this provision.

Citizen Suits. The legislation would authorize any person to bring a Federal lawsuit against EPA or a pesticide manufacturer for any alleged FIFRA violation, be it statutory or regulatory in nature. The consequences of this new authority are likely to be expanded and frequent, frivolous litigation tying up Federal courts and confusing EPA enforcement priorities at large cost to producers and ultimately consumers is a certainty. The bill's whistle-blower provision would further exacerbate these concerns. With all the regulatory restrictive provisions built into the EPA Pesticide Program, this provision is unnecessary and will foster further delays in research and the marketing of pesticide products.

Pesticide Recordkeeping. The bill greatly expands FIFRA recordkeeping requirements by moving from "certified and individual applicators" to all "pesticide and individual users." This a potentially costly and burdensome new requirement with out any corresponding recognizable environmental or public health benefit. It should be deleted.

ANTIMICROBIAL REGISTRATION REFORM

Mr Chairman, CSMA has for the past 18 months worked with the Chemical Manufacturers Association (CMA), the Soap and Detergent Association (SDA), and the International Sanitary and Supply Association (ISSA) in a coalition known as the Antimicrobial Industry Coalition (AIC). We have demonstrated the severe problems which plague EPA's pesticide registration program. We have put forward a legislative proposal which would streamline the antimicrobial registration process without compromising the integrity of scientific review or public health. Many of the ideas contained in the AIC legislation, in fact, are reasonably consistent with the underlying principles of Assistant Administrator Goldman's own streamlining effort now underway at the Agency, and we are actively engaged in a dialogue with her staff.

The need for this legislation became apparent to us as a result of the unacceptable backlog in antimicrobial applications pending within the Agency with little or no chance to evolve within a reasonable time. The extent of paralysis became evident when it came to light that only eight new antimicrobial active ingredients have been registered by EPA within the last 10 years; while approximately 120 new nonantimicrobial active ingredients were registered for use in other types of pesticide products. This is not to indicate that this latter figure itself is reasonable but merely shows the problem facing the antimicrobial active ingredient producers.

The problem, however, also extends into end-use products where applications remain locked up within the Agency for unreasonable periods of time and the expedited review provisions of the 1988 amendments remain largely dysfunctional. With

little aspect of obtaining registrations within a reasonable time period, new research and development activity on antimicrobials has been severely curtailed. The result is that the use of new antimicrobial active ingredients in formulated products which may pose reduced risks as advocated by EPA are not progressing through the pipeline to the end-use consumer. Thus, as we have repeatedly said in every hearing for the past 15 years, something must be done about the registration process within EPA. If the Agency really wants to spur on the introduction of products posing reduced risks, then it must address this registration process. Its inability to do this over the last 15 years, despite the 1988 amendments to FIFRA, dictate that this subcommittee move forward and address this problem now in new legislation.

Among the most serious problems with in Office of Pesticide Programs antimicrobial registration process are: 1) inadequate staffing and resources, 2) unnecessary, repetitive reviews of staff actions, 3) EPA's low priority treatment of antimicrobial applications, and 4) shifting data requirements which change without scientific justification. Our understanding is that the Registration Division's Antimicrobial Branch has had only two product managers attempting to handle 2600 product registrations and amendments each, while nonantimicrobial product managers handle approximately 1500 product decisions. In short, EPA has not assigned sufficient staff personnel to handle the volume of applications and amendments for these products in a reasonable time period.

With respect to staff priorities, EPA has focused its resources on the registration and reregistration of agricultural chemicals which the Agency has concluded presents the greatest public health and environmental risks and similarly the greatest opportunity for risk reductions. Under this system, applications and amendments for antimicrobial products experience unreasonable delays awaiting EPA staff action. Once actions are finally taken the system is plagued by consecutive reviews by several layers of EPA management. Finally, once actions have been taken, applicants often find themselves caught in the dilemma of having data requirements changed by EPA staff without scientific justification with additional studies demanded which in many cases, are irrelevant to a product's proposed use. Registrants experience unconscionable delays as a result of EPA request for clarification, raw data, and imposition of additional data requirements. All of these factors combine to keep these products from the marketplace because of failure to obtain registration within a reasonable timeperiod. The irony of the situation is that many of the products have cleaning and detergent capabilities which, absent the disinfectant claim, are available without any prior approval from EPA for sale to consumers.

The Antimicrobial Industry Coalition bill seeks to address these shortcomings by significantly streamlining the registration process by establishing:

— A statutory definition for antimicrobial pesticides which appropriately distinguishes the unique uses and benefits of anitimicrobials from those of other pesticides;

— A new division of antimicrobial pesticides to clarify, improve and consolidate regulatory requirements. This division would be provided with staff and resources adequate to permit timely and consistent decisionmaking on the large volume of antimicrobial registration applications. These resource allocations, would more equitably reflect the fees contribution of the antimicrobial pesticide industry;

— A registration process for antimicrobial pesticides recognizing unique uses, limited risks and societal benefits of this pesticide class without compromising scientific review of data necessary to maintain or establish public health and environmental standards;

— A process emphasizing from-end agreement between the registrants and EPA concerning data requirements and schedules for decisionmaking. This would provide certainty and finality and would be subject to EPA dispute resolution procedures and judicial enforcement;

— A regulatory program whereby applicants can certify compliance with specified EPA requirements or in some cases notify EPA of compliance thus freeing EPA personnel to address registration health related reviews.

I wish to emphasis the need for inclusion of antimicrobial registration reform amendments to FIFRA in whatever markup vehicle is chosen. CSMA believes these problems need to be addressed in 1994, whether or not comprehensive food safety legislation is completed this year.

OTHER AREAS NEEDING SUBCOMMITTEE ATTENTION

There are a few other areas in the regulation of pesticides which warrant subcommittee attention. These points and suggested remedies are as follows:

Expedited Review. The 1998 FIFRA amendments, under section 3(c)(3)(B) created and "expedited review" for registration applications which are identical, or substantially similar, to a currently registered pesticide product. FIFRA now requires that the applicant receive notification from the Agency as to whether or not the application is complete within 45 days and subsequent to such determination, that these applications be approved or denied within 90 days. This process is not working and thus even simple label changes and applications to register products which are identical to other previously registered products can take over a year to complete. Congress created expedited review and specifically earmarked $2 million to eliminate registration backlogs in 1988. Yet nearly 6 years later, EPA is still not utilizing this tool.

CSMA recommends that the subcommittee legislatively compel EPA to implement a procedure whereby under FIFRA section (3)(c)(3)(B)(ii)(I), any applicant who does not receive notification within 45 days after EPA's receipt of an application as to whether or not the application is or is not complete, then such application must be deemed by EPA as complete. Furthermore, in the event that the applicant does not receive notification as to the acceptance or denial of the application within 90 days after receipt by EPA of the complete application, then pursuant to FIFRA section (3)(c)(3)(B)(ii)(II), such application must be deemed by EPA as approved.

Under this suggested procedure, which follows the times mandated by Congress under the current law, EPA should be permitted to only refuse to issue and approved application after expiration of 90 days if the Agency, within 15 days, was planning to issue a Notice of Intent to Suspend or Cancel the active ingredient registration for the same uses. The deadlines set forth could not be extended by EPA for reasons having to do with administrative workload. Furthermore, in the event of a new registrant wishes to obtain a stamped approved label for use in the States, it could do so by merely having an agent present such label for appropriate stamping at an EPA designated office.

Under this suggested procedure, hundreds of applications for products which are similar or identical to those already registered and on the market would move quickly. Implementation of this procedure would therefore greatly assist in breaking the EPA registration log jam which is precisely what this subcommittee and Congress directed EPA to accomplish nearly 6 years ago.

Certification and Training. In past FIFRA hearings, there has been some discussion concerning certification and training requirements and whether these should be extended to persons using general use pesticides. Some interests have advocated that commercial application of any pesticide should be made subject to certification and training standards even if the pesticide is applied incidental to employment.

Implementation of such a policy would be folly and would require certification and special training for persons such as:

— A busboy in a restaurant who wipes table tops with a disinfectant cleaner;

— A school custodian who cleans the rest rooms with a tile and bowl cleaner;

— A building superintendent who eradicated a hornets nest with general use wasp and hornet spray;

— A nurse or doctor using a hospital disinfectant; or even a housekeeper who freshens up a room with a disinfectant spray.

In each of these instances, the pesticide applied is a general use product under section 3 of FIFRA, registered as such because EPA has reviewed it and determined that it will not cause unreasonable adverse effects to man or the environment. Such factors as low toxicity, when compared to other pesticides that may be classified as restricted use, are already taken into account. EPA also approves the label and specific directions for use.

Consumers of general use pesticides can be expected to use the products safely in accordance with directions without costly and burdensome training and certification. It is not necessary or appropriate to burden the public with such requirements, which would limit an individual's ability to *quickly, easily,* and *inexpensively* solve pest problems affecting public health and safety.

We believe that certification and training requirements are appropriate for "commercial applicators" who apply pesticides as the principal part of their business and we believe any legislation concerning such certification and training should reflect this distinction.

Conclusion

I want to close by emphasizing the need for consideration of our suggested changes and inclusion of antimicrobial registration reform amendments to FIFRA.

We believe that these problems can and need to be addressed in 1994, whether or not comprehensive food safety legislation is completed this year.

Christian Schlect and Mark Maslyn

The Minor Crop Farmer Alliance (MCFA or Alliance) comprises 134 local, regional and national commodity organizations interested in solutions to the minor use issue.

The Alliance, representing organizations that grow and market agricultural commodities, was formed in November 1991 to address legislative and administrative policies to ensure the continued availability of crop protection chemicals for minor use crops. Although the Alliance's focus is on addressing proposed changes to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the MCFA also addresses other issues to achieve its objectives. These include funding for agricultural research, harmonized international agricultural chemical standards, support for integrated pest management, and any needed reorganization of existing Federal departments or agencies to make them more efficient in addressing crop protection issues.

In summary, when we talk about the minor use pesticide issue, what is meant is the loss of crop protection tools, not for safety reasons but for economic reasons. Basically, the costs of generating data to satisfy the U.S. Environmental Protection Agency's (USEPA) requirements for either registering or re-registering crop protection tools for a particular use outweighs the return that the agricultural chemical manufacturer expects from the sale of that product. For example, if it costs $100,000 to develop data to support a particular minor use pesticide and sales for that use are $75,000, clearly there is an economic disincentive for the manufacturer to develop the required data. This problem applies to both obtaining registrations for new uses and maintaining existing registrations. Over the past 5 years, this issue has become particularly acute.

According to the National Association of State Departments of Agriculture (NASDA), a member of the Alliance, the lack of sufficient minor crop pesticides has two added impacts. The first impact is on State resources, in that State personnel must be devoted to the development of requests for section 24c and section 18 exemptions, most of which are in response to minor crop pest control needs.

The second impact is on pesticide investigation and enforcement efforts. States must pursue cases of label violation where the pesticide is not registered on the crop subject to the investigation, but is labeled for use on similar crops. Civil penalties are imposed for violations such as the application of Ronilan on blackberries, although it is labeled on strawberries and raspberries, or the application of Lorox on celery, which is labeled for celery application east of the rocky mountains only. The end result is that crops are embargoed and civil penalties can be levied although the violation is primarily technical in nature. In most instances, economics is the reason why a product is not on the label.

We would like to focus now on the legislative solutions to the minor use pesticide issue which we believe can and must be enacted this year.

House bill H.R. 967 by Congressman de la Garza, Roberts, Stenholm and Smith has 128 cosponsors. The companion Senate bill, S. 985 by Senators Inouye and Lugar has 43 cosponsors.

The Minor Crop Pesticides Act would essentially:

(1) Define minor uses to include those noneconomic uses involved on commercial agricultural crops or sites, on animals, or for public health.

(2) It would extend exclusive data protection for 10 years when such data relate solely to a minor use pesticides. For instance, when a manufacturer registers a pesticide for the first time, EPA is required to maintain their data in confidence. Competitors can rely on those data only after a certain time period, *i.e.*, after 10 years have elapsed, or if the original data submitter voluntarily allows them access. The legislation would provide additional protection for data relating to minor use pesticide information.

(3) The legislation would extend the time for submission of residue chemistry data for minor use pesticides for 2 years after the final deadline for submission of data for the major pesticide uses. Basically, this would establish two categories of pesticide information, one for major uses and the other for the minor uses. The pesticide manufacturers have indicated that it would be beneficial if they would be allowed to complete the re-registration process by developing the data necessary to support their major uses first, and then subsequently supply the data necessary for supporting the remaining minor uses.

(4) The legislation would expedite minor use pesticide registration decisions in three instances: (1) if there are three or more minor pesticide uses per major use, (2) if the use would serve as a replacement for a use that has been cancelled within 5 years of the application, or (3) the use would avoid the re-issuance of an emergency exemption. I think that makes sound public sense. If the USEPA is going to cancel a particular chemical or if the USEPA, which has been under much criticism lately for continually issuing emergency exemptions for pesticide uses, can get uses addressing those circumstances registered, registration applications for those uses should receive a priority.

(5) The legislation would also authorize the conditional registration of minor pesticide uses that were previously cancelled or proposed for cancellation or deletion after December 24, 1988. Essentially this would return to the market for a period of time certain chemicals that were previously cancelled where a clear determination that no safety triggers were exceeded can be made.

(6) The legislation would also provide a temporary extension of unsupported minor pesticide uses to the final deadline for submission of data for uses being supported. This is a transition period provision. In other words, what is needed in the farmer community is early notice that a particular chemical is being eliminated. Manufacturers have a reason not to provide that notice. When pesticide manufacturers decide not defend a particular pesticide use, sometimes they wait until they submit their voluntary cancellation request to the Agency prior to notifying user community of the loss of a use. There needs to be a better communication system, a warning system that identifies when a particular use is going to be lost at the earliest possible time.

(7) The legislation would also establish USEPA and USDA minor pesticide use programs. It is important that those two agencies cooperate. As strange as it sounds, in Washington, D.C., the USDA and USEPA may not always talk to one another. As a matter of fact, often they talk at one another, if they talk at all, and that has to change. This is not good for farmers or for the regulated community or any other parts of our society. Both Federal entities have an opportunity to do great good or great harm. We would suggest that they focus on doing the greater good, and one way they're going to achieve that is by coordinating their efforts in the pesticide area.

(8) The legislation would also provide a matching fund for data development with industry and the USDA. If minor use data are required, under a matching program a grower organization, for example, could put up half the money with the Government putting up the other half. The growers would then repay the Government share over a longer period of time, *e.g.*, 10 or 20 years.

(9) The Minor Crop Farmer Alliance also wants an increase in funding for the IR–4 program and have additional funds devoted to the IPM programs. We think these are very important.

(10) We would also support expedited treatment of biologicals and so-called reduced risk chemicals.

As a solution to the minor use issue, some have suggested simply increasing exemptions from data submission for a number of these minor uses. If EPA does not require so much data, the potential economic impact would be addressed. However, pesticide uses associated with fruits and vegetables are those that are in the public's mind. If a residue problem comes up, you normally don't hear about it in reference to Christmas trees. You hear about it developing on fruits, vegetables and specialty crop foods that people typically consume. The publicity is particularly intense if it involves children. The Alliance supports those actions necessary to protect the health and safety of our food supply and will work with the administration to develop a comprehensive approach necessary to assure the consuming public of the safety products we grow.

The minor use provisions in the administration's proposed pesticide/food safety reform legislation are a major step forward. We are encouraged by the administration's recognition of the minor use problem by including many of the provisions of H.R. 967 and S. 985 in its proposed legislation.

We look forward to continued discussions with the Congress and the administration regarding these provisions. It is imperative that reasonable changes in the process for minor uses be made this year.

Attached to our testimony is a revised chart comparing the Minor Crop Farmer Alliance (MCFA) proposals contained in H.R. 967 and S. 985 with the administration's proposals contained in H.R. 4329 and S. 2050.[21] Based upon a review of the administration's proposals, the following comments are offered for your consideration:

1. *Section 10 Minor Use of Pesticides (a) Definition, p. 74.* The Agency has established criteria by which a pesticide use is automatically considered a minor use (a "bright line"). There are problems with the criteria. First it does not relate to use of a pesticide on a site, on an animal or for the protection of public health. Those uses would have to qualify under the second part of the definition, namely that the use does not provide sufficient economic incentive for its maintenance. It is recommended that the criteria be revised to also create a "bright line" to address sites, animals and to protect the public health. Additionally, the farm gate value or potential return to the crop on an annual basis should be dropped from the definition. It simply is an unnecessary restriction. Further, the higher this value is in relation to the acreage of production, the greater the negative impact on the availability of crop protection tools due to liability concerns.

2. *Sec. 10 Minor Use of Pesticides (a) Definition, p. 74.* The second part of the definition of a minor use is an economic definition *i.e.*, the use does not provide sufficient economic incentive for its maintenance. However, the definition adds three additional criteria, any one of which most also be met namely, (a) there are insufficient efficacious alternative registered pesticides available for the use, (b) the alternatives to the pesticide pose greater risks to the environment or human health, or (c) the pesticide plays a significant part in managing pest resistance. It is recommended that these three criteria be eliminated. If a pesticide use is shown to be noneconomic, it should qualify as a minor use. The minor use problem is an economic problem. It should not be saddled with additional unnecessary limiting criteria. For example, the criteria that there are insufficient efficacious alternative registered pesticide products available perpetuates making just one potential crop protection tool available for a minor use. Minor uses should not be limited to one pesticide. This can place the affected commodity at risk particularly if questions about that single pesticide ever arise jeopardizing the continued use of the pesticide.

If the criteria are to remain, another alternative criteria should be added, namely that the pesticide is included as part of an Integrated Pest management ("IPM") program.

3. *Section 9 Reduced Risk Pesticides, (g) Use of Research Funds, p. 71.* This provision would authorize use of grower funds for pesticide research and technology transfer plans. However an exclusion exists namely "[n]o moneys under this section may be made available to persons directly or indirectly engaged in the registration of pesticides under this Act for profit." It is not clear what "directly or indirectly" mean. There may be grower associations or organizations which may register pesticides for profit as a small adjunct to the traditional nonprofit activities of the organization. In any event, it is suggested that this sentence be amended to read "[n]o moneys under this section may be made available to persons whose business substantially involves the sale of pesticides for profit." This should eliminate chemical companies which are the entities at which the provision is presumably aimed.

4. *Section 10 Minor Use of Pesticides (b) Adequate Time For Submission of Minor Use Data, p. 75.* The first sentence of subparagraph (n)(l) should be revised to indicate that the Administrator, on the request of a registrant "or at the request of a user with the consent of the registrant," may delay action to delete a minor food or feed use. This would provide user community greater direct involvement in the extension process.

In addition to the foregoing, consideration should be given to requesting Congress to modify the administration's bill to add a number of provisions included in H.R. 967 and S. 985 which are not yet part of the administration proposals. In particular, the proposed grant program and the establishment of minor use programs within both EPA and USDA should be included by the Congress.

In conclusion, Mr. Chairman, we believe that the differences between S. 985 and the minor use provisions of S. 2050 the Administration bill, quickly resolvable. We believe this issue can and should be resolved this year and we look forward to working with you and Chairman de la Garza to enact minor use legislation this year.

[21] See page 91.

OUTLINE OF MINOR CROP PESTICIDES ACT (MCFA)
WITH ADMINISTRATION PROPOSALS

MCFA	ADMINISTRATION
1. Minor use defined and based on lack of economic incentive to maintain the use.	1. Minor use defined both as a "bright line" and as an economic problem. The "bright line" definition includes qualifiers i.e. To automatically be considered a minor use, the total acreage of the crop must be less than 300,000 acres and the average annual production value of the crop must be less than $500,000,000. Another way to qualify as a minor use is to demonstrate that the use does not provide sufficient economic incentive to support the use. In addition, in such circumstance, one of three other criteria must be met i.e. (a) lack of efficacious alternatives, (b) alternatives pose greater risk to the environment or public health or (c) the pesticide has a significant role in managing pest resistance.
2. Minor use includes use on animals, commercial agricultural crop or site, or for public health.	2. Minor use includes use on a commercial agricultural crop, on an animal, or for the protection of public health.
3. Exclusive data use protection extended for 10 years if such data relate solely to a minor use. Includes new registrations and existing registrations.	3. Extend exclusive data use protection for two years for those pesticides for which the Administrator has approved at least three minor uses prior to the expiration of the original exclusive use period, i.e. within 10 years of the date the first use of the chemical was registered.
4. Extend time for submission of residue chemistry data for minor uses for 2 years after final deadline for submission of data for other uses.	4. Extend the time for development of residue chemistry data for minor uses until the last study date for the chemical.
5. Administrator may waive minor use data requirements in certain circumstances.	5. Not discussed. (Essentially in current regulations).

MCFA	ADMINISTRATION
6. Expedite minor use registration if active ingredient is to be registered solely for minor use or if there's 3 or more minor uses for every non minor use, use would serve as a replacement for any use that has been cancelled within 5 years of application or minor use would avoid re-issuance of an emergency exemption.	6. Prioritize pesticide applications as follows: (a) those that would replace the need to issue a § 18 emergency exemption (b) those that reduce risks for pesticides in a cancellation or suspension proceeding (c) reduced risk pesticides (d) minor use pesticides (e) other applications
7. Conditional registrations for minor uses shall be granted in certain circumstances.	7. Not directly discussed.
8. Administrator may conditionally register minor uses that were previously cancelled, proposed for cancellation or deleted after December 24, 1988.	8. Not discussed.
9. Temporary extension of unsupported minor uses to final deadline for submission of data for uses being supported.	9. Allow minor uses to continue until the due date of the final study required in the re-registration process.
10. Utilizing data for voluntarily cancelled chemicals.	10. Not discussed.
11. Establish EPA minor use program and USDA minor use program.	11. Not discussed. (USDA reorganization plan would include parts of the USDA minor use program).
12. Matching fund for data development with industry and USDA.	12. Not discussed.

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William C. Balek

INTRODUCTION

My name is William C. Balek and I am the director of Legislative Affairs for the International Sanitary Supply Association (ISSA). ISSA is a nonprofit trade association comprised of over 4,000 member companies located across the Nation. The vast majority of these companies are small businesses, 68 percent of which have annual gross revenues of less than $2 million.

These companies manufacture and distribute a wide spectrum of institutional and industrial cleaning and maintenance products, including antimicrobial pesticide products such as disinfectants, sanitizers, and germicides which are regulated by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Our membership distributes antimicrobial pesticides for use in hospitals, nursing homes, schools, food and beverage processing plants, hotels, restaurants, day care centers, and other institutional and industrial establishments. As such, these products play an essential role in maintaining public health and the quality of life.

Of the many benefits of antimicrobial pesticides, none is more important than the role played in the protection of public health. Microorganisms exist virtually everywhere. The uncontrolled growth of bacteria, fungi, viruses, and a host of other organisms would have a severe negative impact on public health as well as detrimental economic consequences. Fortunately, this potential impact can be minimized by the proper use of antimicrobial products.

Disinfectants, sanitizers, germicides and sterilants are antimicrobial products designed specifically to control pathogenic organisms which can be harmful, even fatal, to humans and the environment. Modern sanitation and hygienic practices are one of the reasons for the longer life expectancies and general good health and sanitary conditions we enjoy. A significant aspect of these practices includes the use and application of antimicrobial pesticides.

ISSA appreciates this opportunity to testify and we thank Chairman Daschle and the Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation for conducting hearings on the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In our testimony here today, we would like to address certain elements contained in S. 2050 including the fee and labeling provisions. In addition, we would also like to comment on improvements to the product registration process.

PESTICIDE FEES

ISSA strongly opposes the creation of additional pesticide fees and the extension of existing maintenance fees as contemplated by S. 2050. We ask Congress not to grant EPA the authority to impose additional fees upon industry until the Agency provides a detailed accounting of the revenues it collected and expended in furtherance of the pesticide registration program. In fact the House Agriculture Subcommittee on Department Operations and Nutrition recently rejected similar fee provisions when it marked up its version of FIFRA legislation. Furthermore, we oppose any fee provisions, such as those contained in S. 2050, that do not address the disproportionate burden placed upon small businesses.

Over the past several years, EPA has repeatedly declared that it is experiencing a shortfall of revenues necessary to complete its reregistration program. In fact, such a declaration gave rise to a compromise fee package that was adopted in 1991.

In 1991, ISSA and several other trade associations negotiated a compromise on maintenance fees with EPA that was ultimately signed into law. In essence that compromise fee package maintained the maintenance fee at $650 for the first product, and $1,300 for each additional product. These fees are subject to limitations. Small businesses with 50 registered products pay no more than $38,500, while small businesses with 51 or more products pay no more than $66,500. This fee structure generated $15.1 million, $1.1 million more than the statutory goal of $14 million.

Once again, appearing before a joint House-Senate Congressional committee hearing on September 23, 1993, EPA estimated that the current reregistration shortfall was $20 million. The fee provisions of S. 2050 are intended to address this shortfall by extending EPA's authority to levy maintenance fees for 2 years. In addition, S. 2050 would impose a $120,000 supplemental reregistration fee on an active ingredient registered for a major food or feed use, and a $60,000 supplemental reregistration fee for active ingredients registered for nonagricultural uses. Furthermore, S. 2050 would establish a $750 per product fee which could be adjusted by EPA to ensure that at least $4 million would be generated over the 4 year period following enactment.

Based on these fee proposals, we estimate that total revenues of over $60 million will be generated, substantially more than the $20 million shortfall declared by the Agency. We base our estimate on the following. First, it is proposed that the maintenance fee provisions be extended for 2 years. Presently, maintenance fees generate $15.1 million per year. Extending EPA's authority to levy this fee for 2 years would raise an additional $30.2 million.

second, the proposed supplemental reregistration fees of $120,000 and $60,000 are set at approximately 80 percent of the original reregistration fees enacted in 1988. When one considers that in 1989 EPA collected $35 million in reregistration fees, we can expect to collect approximately $28 million, or roughly 80 percent of the 1989 levels. Last, the proposed product registration fee of $750 is designed to generate $4 million.

Based on these calculations, the proposed fee provisions of H.R. 4329 would generate $62.2 million, over $40 million more than EPA's estimated shortfall. This glaring inconsistency, alone, demonstrates the need for a complete explanation of expenditures for the registration and reregistration programs including expenditures for expedited registrations (*i.e.*, "fast track" registrations). ISSA urges Congress to require EPA to provide a clear and detailed accounting of how moneys have been spent since the reregistration program was created under the 1988 amendments to FIFRA. Once we have a clear understanding of the costs and expenditures associated with the reregistration program, we can determine if there is a need to generate additional revenues. To enact fees as contemplated by S. 2050 without the benefit of such an assessment would be premature.

Furthermore, EPA's declared need for additional revenues must also be viewed in the context of EPA's present efforts to "reinvent" the Agency. Like all other Federal agencies, EPA is attempting to streamline its operations to create a more effective and efficient Agency. In essence, EPA is restructuring itself so that it can do more with less resources. We commend EPA for these efforts, and in fact have been working with the Agency to help develop specific proposals.

EPA has responded positively to many of industry's suggestions and is proceeding at an aggressive pace to implement various recommendations. In fact we expect EPA to implement a number of changes within the next 4 to 6 months. For example, the Agency is proceeding with procedures that would allow simple amendments to product registrations to be handled by notification. The Agency is also working to implement process improvements in regard to acute toxicity reviews and the labeling review process.

It is our belief that these and other proposed changes will streamline the operations of the Office of Pesticide Programs (OPP) by improving certain efficiencies and eliminating unnecessary waste of limited Agency resources. It is likely that many of these changes will result in savings to the Agency. Consequently, ISSA believes that it would be best to first evaluate the results of the administrative improvements EPA is attempting to implement before we assess EPA's declared need for additional resources.

More specifically, ISSA strongly believes that it is premature to address the continuation of maintenance fees at this time. An extension of EPA's authority to levy maintenance fees until 1999 does not have to be considered until we move closer to that date. In fact, there will be additional opportunities to review this issue prior to 1998 during additional FIFRA reauthorizations. At that time Congress will have the benefit to see what impact the various streamlining reforms have had on OPP resources, and will be in a better position to judge the need for additional resources.

Moreover, it is important to note that EPA is seeking an extension of maintenance fees until 1999, but it is not seeking an extension of the prohibition of registration fees during the same time period. Therefore, under S. 2050, registrants would have to pay both maintenance fees and the new product registration fees.

The consequences of such a fee system are especially burdensome to small businesses who produce low volume antimicrobial pesticides. In effect, under S. 2050, these companies will have to pay an annual fee of $2050 to maintain their product registration (*i.e.*, a $1300 maintenance fee and the proposed $750 registration fee). To understand the true impact of this proposal we need to place it in the context of State registration fees. It now costs well over $5,000 to register one pesticide product in each State. Therefore, the total cost to a firm who wishes to market its product nationally would be $7,050.

As mentioned previously, ISSA is comprised primarily of small businesses, the majority of which generate less than $2 million per year in the sales of cleaning and maintenance products. Furthermore, antimicrobial pesticides are produced in low volumes. The specialty market in antimicrobial products has been successful because small formulators have been able to produce minimum quantities of antimicrobial products for limited uses. Many of these products generate annual

sales that are measured in the tens of thousands of dollars. These products must pay the same fee as agricultural pesticides that generate sales in the millions of dollars.

Therefore, the pesticide fee provisions of S. 2050 would have an unreasonably disproportionate adverse economic impact on small formulators of antimicrobial products because the fees paid by these companies represent a substantially higher percentage of their total sales compared to larger companies. Such a fee system upsets the competitive balance between large and small firms. Therefore, ISSA opposes any fee system that does not take into consideration small business concerns.

ISSA encourages the Subcommittee on Agricultural Research, Conservation, forestry, and general Legislation to reject the fee provisions of S. 2050. In fact, the House Agriculture Subcommittee on Department Operations and Nutrition rejected similar fee provisions when it completed its markup of FIFRA legislation, H.R. 1627.

LABEL CALL-IN AUTHORITY

ISSA supports the proposed language in S. 2050 that would establish a uniform compliance date for label changes intended to reduce potential risk associated with the use of a pesticide. However, we strongly object to the creation of new suspension and recall authorities which would allow the Agency to take drastic action against pesticide products sold or distributed in violation of the label call-in provisions of S. 2050.

Over the past few years, ISSA has advocated the adoption of a uniform compliance date for label changes required by EPA to reduce the burden of multiple label changes that may be require over the course of a year. To this end we support those provisions in S. 2050 which would set one annual date by which registrants must comply with EPA mandated label changes intended to reduce potential risk associated with the use of a pesticide product.

While we applaud this proposal, we believe it should be expanded upon by establishing an office within EPA that would be responsible for coordinating all EPA required label changes. ISSA believes such an office is necessary because there are numerous offices and programs within EPA that require modification to existing pesticide product labels, but there is no internal coordination of these various label changes.

EPA requires, at various times, numerous amendments to existing labels. The changes might reflect a new active ingredient, an inert or a different use. Other changes are made to incorporate a new set of directions or warnings about use or specific health and safety instructions. At other times, EPA may require the label to be modified to include new instructions for proper disposal of the container. In addition, specific programs within EPA, such as the Label Improvement Program, also require changes to labeling content.

In essence, many different offices and programs within the Agency require registrants to alter their labels. However, there is no mechanism in place through which the Agency is able to coordinate these various label changes. As a consequence, companies may modify their label to address one program's requirements, only to find several months later that they must, once again, alter their label to comply with another EPA requirement.

This lack of coordination is especially burdensome to ISSA members who formulate and distribute private label products. It is not uncommon for formulators to sell one product under as many as 20 to 30 different private labels. Furthermore, companies may have as many as 100 product registrations. As a result, one label change required by EPA results in the printing of thousands of new labels, only to find that another program or department requires additional changes just a short time later. This lack of coordination often results in a company discarding thousands of dollars in labels because they are made obsolete by another EPA directive.

Moreover, there is a distinct lack of coordination between product managers, Label Improvement Program personnel and other EPA staff in formulating label requirements. This internal lack of coordination often leads to conflicting instructions from various Agency personnel as to specific labeling language for virtually identical products. The result can be confusing and frustrating for industry in its attempts to comply with its labeling responsibilities.

ISSA, therefore, recommends that S. 2050 be revised to establish one office within the Agency that would be responsible for coordinating all label changes required by the various programs and divisions within EPA so that there is no confusion about the necessary elements needed to comply with the various EPA required label changes.

Despite the positive move in establishing one uniform compliance date for label changes, ISSA takes exception with those provisions of S. 2050 that would authorize

EPA to suspend and recall pesticide products that are sold or distributed in violation of the requirements issued pursuant to the label call-in provisions of S. 2050.

Under current law, only those pesticides that are suspended or canceled for health and safety concerns can be made subject to a mandatory EPA recall. S. 2050, as drafted, however, would expand the scope of products which could be subject to a mandatory recall to virtually any pesticide with any labeling violation, no matter how minor. As a matter of policy, we should not subject a minor labeling violation to the same penalties as those that apply to products suspended and canceled because of health and safety concerns. ISSA, therefore, encourages Members of the subcommittee to reject those provisions that would allow for the recall of pesticide products for even the most minor oversights in complying with labeling directives.

For essentially the same reasons, ISSA also opposes those provisions of S. 2050 that would allow EPA to issue a suspension notice for even relatively minor inadvertent label violations. Under present law, EPA may issue a suspension notice only if the Agency determines that a product poses an "imminent hazard." S. 2050, however, would expand the Agency's authority to suspend products that had even the most minor of labeling violations regardless as to whether it had an adverse impact on health and safety. ISSA opposes any attempt to expand its suspension power to cover such minor labeling violations.

IMPROVEMENTS TO EPA REGISTRATION PROCESS

EPA pesticide product registrations are not being processed in the most effective and efficient manner. These circumstances have created a backlog of registrations which has had a disproportionate impact upon antimicrobial products. ISSA, in conjunction with other industry groups, has been working with EPA in developing administrative policies which would streamline the OPP registration program. Specifically, ISSA has proposed that EPA adopt strategies that would allow the Agency to meet the requirements of the "fast track" registration program. In addition, we believe the notification process should be broadened to encompass relatively minor registration activities.

Antimicrobial products have been unreasonably adversely affected by the backlog in the EPA registration process. Disinfectants, germicides, sanitizers and other antimicrobial products provide substantial public health benefits by preventing or destroying bacteria, fungi, viruses, and other dangerous microorganisms such as legionella and salmonella. These products play an essential role in the maintenance of sanitary and healthful conditions in hospitals, nursing homes, schools, day care centers, food and beverage processing plants, restaurants, hotels, and many other institutional and industrial establishments and even private homes. In a very substantial way, these products contribute to the overall quality of life that we enjoy today.

Despite these significant benefits, EPA assigns antimicrobial products a low priority in the registration process because of the low risk associated with these products. Unlike other pesticide products, antimicrobials are considered low risk for many reasons:

1. Applications of antimicrobials are generally indoors and in very small quantities, resulting in minimal exposure to the environment and man.

2. Dietary exposure is not a concern with this category of products.

3. In general, antimicrobials are formulated in a manner to provide for their safe use by minimizing the amount of active ingredient present in the product.

4. Industrial biocides are generally used in closed or controlled systems (*i.e.*, water cooling systems, or product preservation uses) which virtually eliminate risks to human health and the environment.

As a pesticide class, antimicrobials provide substantial societal benefits while presenting minimal hazards to man or the environment. Ironically, EPA's policies have frustrated the introduction of significant new antimicrobial products. In fact, during the past 8 years only one new antimicrobial active ingredient has been registered by EPA. By comparison, during that same time period approximately 100 new nonantimicrobial active ingredients were registered.

Antimicrobial pesticides account for approximately 35 percent of all active ingredients and pesticide products currently registered under FIFRA, and generate about $4 million in annual maintenance fees out of a total of $15 million in fees collected annually. At the present, the EPA Registration Division's Antimicrobial Branch has only two product managers attempting to handle 35 percent of registered active ingredients. The other two registration review branches handling the remaining 65 percent of registered actives and products are manned by nine product managers. Consequently, each of the two antimicrobial product managers is responsible for

about 3,500 registrations, while each of the product managers handling other pesticides are responsible for less than 1,400 registrations.

This disproportionate skewing of resources has virtually paralyzed the registration of antimicrobial products. Not only has EPA's policy thwarted the timely introduction of new products and active ingredients, but it has frustrated the timely filing of minor amendments to existing registrations. A recent survey of ISSA members reveals that registrations for minor amendments that could literally take 15 minutes to process are taking anywhere from 6 months to up to 1½ years. The primary reasons for these delays as cited by survey respondents include:

1. Inadequate number of personnel.
2. EPA's claim of lost mail or paperwork requiring the need for resubmission.
3. Inconsistent requirements for labeling language and data.

One respondent pointed out that it has repeatedly taken approximately 1 year for it to receive approval for its "me-too" antimicrobial registrations. However, the same company has been able to receive approval for a nonantimicrobial product "me-too" registration in just over 3 weeks.

These delays are not only inequitable but are also unacceptable. The EPA registration process must be improved and not continue to operate as a barrier to market entry thereby denying the public access to better products. ISSA suggests that Congress direct the Agency to make improvements to the "fast track" registration program as well as expand the scope of registrations that could be handled by a notification process.

FAST TRACK REGISTRATION

For the past 6 years, EPA has been attempting to implement the provisions of the 1988 amendments to FIFRA which require the Agency to expedite "me-too" registrations and other minor amendments. To date, EPA has been unsuccessful in executing this Congressional mandate. Fast track registration requires EPA to expedite the processing of product registrations that are identical or substantially similar to existing pesticide products and for which no scientific review of data is required.

Under this expedited process, EPA must inform the registrant within 45 days as to the completeness of the application. EPA then has 90 days to approve or deny the application for registration. Although EPA has complied with the 45 day limitation, it is rare that the 90-day deadline is met by EPA. As described previously, ISSA members have pointed out numerous instances where it has taken 6 months to 18 months to process their fast track registration. This delay creates an anticompetitive situation, especially for a small company whose only advantage is the speed with which they can bring a product to market. More importantly, this situation denies the public the benefit of new and improved products.

In order to address these shortcomings, ISSA suggests that existing resources within OPP should be used to address the backlog of fast track registrations. Assignments of specific personnel to handle fast track registrations should be made. For instance, one person on a product manager's team should be designated to process expedited review registrations. When that person has relieved the backlog, he or she can be returned to other team assignments. In addition, ISSA encourages EPA to devote staff and resources adequate to permit timely and consistent decisionmaking on the relatively large volume of antimicrobial registrations. Resource allocations should more equitably reflect the amount of fees generated by antimicrobial products.

Furthermore, under present processing of me-too applications and simple amendments not requiring scientific review, each of these fast track registrations is placed in one stack with all other applications. ISSA believes that EPA should institute a two stack approach: one for fast track registrations and another for other applications. This process would help ensure that fast track registrations are not lost in the crowd and are given the proper attention.

Under present policy, EPA uses a seven step review process for all registrations including fast track. Such a process is unnecessary for most fast track registrations because a decision can often be made early on in the process. Consequently, the seven step process unreasonably adds to the length of time necessary to process a fast track registration. ISSA encourages EPA to provide a first level reviewer with the authority to complete the process at the first step thus avoiding undue delay.

ISSA also believes that the color coding of fast track registrations would help ensure their expeditious processing of fast track registrations so that they can be more easily recognized. In the alternative, a pressure sensitive "tab" can be attached to the application. Either one of these alternatives would allow for the fast track registration to be more readily distinguishable. At the present, a fast track registration

application is virtually indistinguishable from other registrations increasing the likelihood of it not being processed in a timely fashion.

Lastly, we believe FIFRA should be amended such that if the Agency fails comply with the 90 day fast track deadline that such application should be deemed granted. At the very least, EPA should be required to provide the registrant with an update and an expected timetable for completion. Such information is essential for registrants to make calculated business decisions. At the present, no such communications exist.

To this end, ISSA strongly encourages the subcommittee to adopt section 112 of H.R. 1627 entitled "Requirements for Registration of Substantially Similar or Identical Pesticides and Antimicrobial Pesticides and Products." This provision addresses the shortcomings of the current "fast track" registration system and will instill a sense of equity in the registration process.

EXPANSION OF NOTIFICATION PROCESS

In order to reduce the present backlog and to free up Agency resources for other more important tasks, ISSA strongly believes that the notification process should be broadened in order to expedite common product amendments which do not involve the introduction or increase in risk. ISSA has recommended to EPA that the Agency establish a certification process by which a registrant could certify that its registration application meets the EPA's requirements for registration. The following are some examples of the types of registration activities that should be accomplished through the notification process:

— New areas (*i.e.*, site) or use within the same category not requiring additional data (*i.e.*, hard surface kitchen; hard surface bathroom).

— EPA initiated label changes (*e.g.*, new container disposal regulations).

— Environmental marketing descriptions subject to FTC restrictions.

— Notification or self-certification of acute toxicology studies, except for inhalation and dermal sensitization.

ISSA strongly believes that the expansion of the notification process is essential to reduce the existing backlog so that the Agency is able to free up valuable but limited resources. Just as important, the expansion of the notification process should also help ensure that any future registration backlogs are avoided.

COORDINATION AND SYNCHRONIZATION OF PESTICIDE DATA REQUIREMENTS BETWEEN EPA AND THE STATES

ISSA encourages the subcommittee to approve legislative language which would facilitate the coordination and synchronization of data between the States and the U.S. Environmental Protection Agency. Such coordination and synchronization is essential to avoid redundant testing and unnecessary and substantial expenses.

The present problem is exemplified by California's Birth Defects Prevention Act, S.B. 950. This legislation requires the filling of data gaps for all pesticides including antimicrobial products. In order to implement S.B. 950, California adopted a definition of a "data gap," established a list of tests needed to be completed, and set a time table for filling these gaps. In so doing, the State has disregarded the efforts of Congress in establishing its own expedited reregistration program in the 1988 amendments to FIFRA which were designed to fill essentially the same data gaps.

In effect, California has established an agenda and time table that duplicates and conflicts with Federal requirements. Such inconsistent requirements result in unnecessary, repetitive and redundant testing that not only consumes valuable time and resources but also delays the closing of data gaps. Valuable time and resources that could be used to develop new data are wasted in refocusing on gaps that have already been or are in the process of being filled.

The additional and conflicting data requirements artificially raise the cost of manufacturing and distributing pesticide products. It is important to note that many low volume, low profit specialty antimicrobial pesticides may be discontinued because neither the registrant, the formulator, nor the State will pay for the additional tests required on active ingredients. In fact these additional costs have resulted in the cancellation of numerous antimicrobial product registrations in California. This pattern is likely to continue as other States enter the picture once again forcing other necessary and useful products off the market.

Therefore, ISSA strongly encourages the subcommittee to explore legislation that would facilitate the coordination and synchronization of data requirements between the States and the EPA. Such legislative action will help stabilize the cost of pesticide products by precluding unnecessary and redundant testing, thereby ensuring

the continued availability of a wide range of antimicrobial products. Specifically we urge the subcommittee to adopt the language contained in section 113 of H.R. 1627 entitled "Synchronization and Coordination of Data Between Federal and State Agencies."

PUBLIC HEALTH PESTICIDES

S. 2050 contains a provision, supported by ISSA, which recognizes the need to protect the continued availability of public health pesticides. Specifically, S. 2050 would direct the Department of Health and Human Services and EPA to collaborate in identifying critical public health minor uses that might otherwise be lost and to arrange for necessary data support. In this regard, S. 2050 authorizes appropriations in the amount of $12 million to be used in providing support for the required studies needed to continue the registration of public health pesticides.

ISSA supports the public health pesticide provisions contained in S. 2050. In supporting these provisions, we suggest that the subcommittee incorporate into FIFRA amendments the provisions of H.R. 1867 introduced by Representatives Dooley and Herger, and more formally known as the Public Health Pesticides Protection Act. This legislation ensures that EPA establish guidelines that take into consideration the benefits of public health pesticides, and to ensure that these products are not lost in the reregistration process due to economic reasons alone.

H.R. 1867 was introduced to provide recognition and relief for pesticides registered for public health purposes. The legislation would extend special consideration and protection to pesticide products used to maintain good mosquito and other vector programs. In addition, H.R. 1867 would extend the same treatment to certain disinfectants, sanitizers, and other antimicrobial products.

ISSA supports H.R. 1867 because it recognizes the importance of these products in maintaining safe and healthful conditions in society. These products, however, have experienced tremendous regulatory burdens because they are treated just like agricultural pesticides in many cases. These burdens have become so substantial that many products have been dropped from the market because it is no longer economically feasible to maintain their EPA registration. Consequently, many products essential to the maintenance of safe and healthful conditions will continue to be lost unless some relief is provided.

ISSA believes that H.R. 1867 provides that relief. Specifically, H.R. 1867 would accomplish the following:

— The bill would define "public health pesticides" in the context of minor use to include a pesticide which is used in the prevention or mitigation of viruses, bacteria, or other microorganisms that pose a threat to public health.

— Create a separate class of pesticide registration for public health pesticides with a risk benefit analysis, separate and distinct from that utilized for agricultural pesticides.

— Expedite the registration of pesticides necessary for public health protection.

— Require EPA to take into consideration the differences in concept and usage between agricultural, nonagricultural, and public health pesticides.

— Require EPA to consult with the Secretary of Health and Human Services on pesticides for public health uses.

For these reasons, ISSA seeks the inclusion of H.R. 1867 into any set of FIFRA amendments the subcommittee ultimately approves.

Conclusion

ISSA commends the subcommittee for conducting these hearing and encourages it to move forward and markup a FIFRA bill as soon as possible. ISSA objects to any FIFRA package that would create new pesticide fees or extend existing maintenance fees. Such action is premature and should only be considered after we have received an accounting from the Agency.

ISSA supports the provision in S. 2050 that establishes one uniform compliance date for label changes. However, we encourage the subcommittee to incorporate language that would establish a central office within the Agency to coordinate all such label changes. We firmly believe such an office is essential not only to address timing problems, but also to address inconsistent labeling language requirements. While we support the uniform labeling compliance date, we oppose those provisions of S. 2050 that would expand the EPA's authority to suspend and recall products whose label may deviate even slightly from the Label Call-In provisions of the bill.

ISSA also encourages the subcommittee to incorporate provisions that would facilitate the coordination and synchronization of data requirements between the State and Federal Governments. Last, ISSA urges the subcommittee to expand on the public health pesticide provisions of S. 2050 by incorporating the language of H.R. 1867.

We thank the Members of the subcommittee for this opportunity to express our views on this subject of utmost concern to our industry.

Warren E. Stickle

INTRODUCTION

I am Warren E. Stickle, president of the Chemical Producers and Distributors Association (CPDA). We at CPDA are delighted to have the opportunity to submit our testimony for the record in response to the July 28, 1994 pesticide hearings conducted by the Senate Subcommittee on Agricultural Research, Conservation, Forestry and General Legislation of the Committee on Agriculture. In our testimony, we will discuss the administration's pesticide legislation as well as a number of related issues of importance to our association.

By way of introduction, CPDA is a voluntary, nonprofit membership association consisting of about 90 member companies engaged in the manufacture, formulation, distribution and sale of some $3.5 billion worth of products used on food, feed and fiber crops, and for lawn, garden and turf care.

Before we share with Members of this subcommittee our thoughts regarding S. 2050 and S. 2084, we would first like to commend you, Chairman Daschle, for moving forward with hearings on this legislation. We look to your leadership to bring together the many divergent views regarding the regulation of pesticides in reaching a fair and reasonable consensus on FIFRA.

We will first turn to S. 2050, the administration's legislation to amend FIFRA. We at CPDA have a number of concerns with this legislation and today we will offer our thoughts on how this legislation could have a severe impact on CPDA members—many of whom are small to medium-sized companies. In discussing the many changes proposed in the administration's bill to amend FIFRA, we will also share with the subcommittee some alternative proposals developed by CPDA which, we believe, will accomplish the common goal shared by all—namely, the preservation of the integrity of our nation's food supply and the increased efficiency and improvement of EPA's pesticide programs. Many of these initiatives have already been incorporated into legislation, H.R. 1627, as amended by the House Subcommittee on Department Operations and Nutrition (DON) during its July 27, 1994 FIFRA markup.

Our other comments will focus on S. 2084, the administration's bill to amend the Federal Food, Drug and Cosmetic Act (FFDCA). CPDA's testimony will address the concept of negligible risk in setting tolerances for pesticide residues in foods and we will examine related food safety issues which include the national uniformity of tolerances and inerts. Again, we thank you for the opportunity to submit CPDA's statement for the hearing record.

PESTICIDE REGULATION UNDER FIFRA

PHASE-OUT/PHASE-DOWN

CPDA is strongly opposed to the provisions contained in S. 2050 which would allow the EPA Administrator to phase-out or phase-down the use or production of a pesticide if scientific evidence indicates that its use is "reasonably likely to pose a significant risk to humans or the environment." In fact, the House Subcommittee on Department Operations and Nutrition rejected these provisions in its recent markup of FIFRA legislation.

First, we at CPDA believe that other safeguards in FIFRA exist which allow the Administrator to address potentially harmful chemicals. For example, current FIFRA already allows the Administrator the authority to place certain restrictions on the use of a pesticide as a condition of its registration. Second, we believe that the improvement of the present cancellation procedures so as to provide a more expedient method for removing bad actors from the marketplace would obviate the need for any provisions calling for a phase-out or phase-down of the use and production of a chemical for which EPA has concerns pertaining to its safety.

Third, the administration's phase-out/phase-down provisions are based on a comparatively lenient standard that a chemical is "reasonably likely" to pose a "significant" risk to humans or the environment. We at CPDA do not believe that it is pru-

dent to proceed with a regulatory action against a chemical which could have a serious adverse impact on growers and other end-users simply on the premise that a product is "reasonably likely" to pose a "significant" risk. Rather than a regulatory standard based on "significant" risk, it should be an "unreasonable" risk. The grave consequences that would result from eliminating or capping the production of a pesticide necessitates that a higher degree of certainty relating to any risk associated with use of that pesticide be adopted. The standard contained in the administration's bill could be abused by those who would advocate a total ban of *all* pesticides and lead to a modern day witch hunt targeting hundreds of necessary and beneficial products which have been in common use for years without resulting in any harm to man or the environment.

We at CPDA agree with the remarks of Representative Robert F. Smith (R–OR), ranking minority member of the House Subcommittee on Department Operations and Nutrition, which appear in the record of that panel's July 27, 1994 FIFRA markup. Representative Smith states, ". . . In addition to my concern that it would encourage EPA to circumvent the FIFRA cancellation process, I believe that a gray area for pesticide registration status, which would be created by the administration's phaseout/phase down is irresponsible. A chemical is either safe for use or it isn't. To further confuse the issue by instituting a 'phase-out' does a disservice to producers, possessors, and consumers. With 'phase-out' the EPA may just want a tool it can use to manage public opinion disasters, but it will come at the expense of sound public policy."

Fourth, the Clinton phase-out/phase-down proposal erroneously equates the elimination of pesticide use with a reduction in risk. Science has clearly demonstrated that such a correlation cannot be made. The curtailment or elimination of a pesticide product from the marketplace could have an adverse impact on a farmer's ability to exercise Integrated Pest Management (IPM). The success of IPM is dependant, in part, on a wide range of pest control tools being made available to the farmer. The disappearance of one product from the farmer's arsenal could actually result in a shift in use patterns to other products which may pose an even greater potential risk.

Finally, we at CPDA believe that careful consideration must be given to the potential economic impacts which would occur if production caps were to be placed on pesticides marketed primarily for export. By far, the regulatory standards of the United States are much stricter than those of many of our global trading partners. The higher cost basis for United States producers who must incur significant capital expenditures to comply with stringent Federal regulatory standards already places domestic manufacturers at somewhat of an economic disadvantage compared to their foreign competitors. We at CPDA believe that it would be unwise to adopt legislation calling for caps on American production which could further erode the position of domestic pesticide manufacturers in the global markets. Such legislative provisions would place American jobs in serious jeopardy at a time when the United States is seeking to strengthen its economy. CPDA strongly recommends that this subcommittee to reject the phase-out/phase-down provisions of S. 2050.

Fees. We at CPDA are adamantly opposed to those provisions of S. 2050 which would provide EPA with additional pesticide fee authority. The House Subcommittee on Department Operations and Nutrition rejected a similar fee provision in its deliberations over H.R. 1627. CPDA members believe that it is premature to create additional fees when the Agency has not yet provided a detailed cost accounting of how and where the moneys collected in the reregistration program have been spent.

In the last 3 years, the EPA has maintained that its reregistration program is experiencing a shortfall of revenues. Three years ago, this deficit was estimated at $160 million, then $100 million, and then $40, $35 and $32 million. Appearing before a joint House-Senate Congressional committee hearing on September 22, 1993, administration officials estimated that the current reregistration shortfall was $20-million. Now, however, it would appear that the fee provisions in S. 2050 are calculated to generate in excess of $60 million in additional fees. CPDA asks that the subcommittee take a closer look at the numbers.

First, S. 2050 provides for a 2-year extension of EPA authority to levy maintenance fees through September 30, 1999. We would like to point out to this subcommittee that back in the fall of 1991, CPDA and four other industry trade groups negotiated a compromise on maintenance fees with EPA. This compromise was ultimately adopted as part of the technical corrections package amendment to the 1990 Farm bill which was signed into law by President Bush.

The compromise package included provisions which:

- adjust the cap for the first 50 products from $20,000 to $55,000, and increase the cap for products 51 or more to $95,000;

- maintain the fee at $650 for the first product, and $1,300 for each additional product up to the adjusted caps;
- establish a small business cap at $38,500 for the first 50 products, and $66,500 for products 51 or more. A small business registrant is a corporation, partnership, or unincorporated business that has 150 or fewer employees and during the last 3-year period had an average annual gross revenue from chemical sales that did not exceed $40,000,000;
- beginning in 1992 and continuing through 1997, adjust the payment timetable from March 1 to January 15, thus allowing the Agency to collect funds earlier to mitigate its existing cash-flow problems;
- allocate one-seventh of the maintenance fees collected by EPA in 1992, 1993 and 1994, and in 1995, 1996 and 1997 up to $2 million annually to accelerate reregistration (Fast Track) and expedited processing of funds.

This amendment package raised $15.1 million thus fulfilling its statutory requirements included in the 1988 FIFRA amendments. In fact, it created a surplus of at least $1.1 million beyond the $14 million required under FIFRA. As such, a 2-year extension of maintenance fee authority, as proposed by S. 2050 can be expected to generate an additional $30.2 million (*i.e.*, $15.1 million/year × 2 years).

Second, S. 2050 calls for a $120,000 supplemental reregistration fee on an active ingredient registered for a major food or feed use and a $60,000 supplemental reregistration fee for active ingredients registered for nonagricultural uses. If two or more registrants are required to pay the supplemental reregistration fee, the fee would be apportioned among the registrants on the basis of United States sales of the active ingredient during 1990–1992. The active ingredient fees set forth in S. 2050 represent levels which stand at about 80 percent of the fees adopted by Congress in enacting FIFRA "Lite" in 1988. If one considers that in 1989, EPA collected some $35 million in active ingredient fees as a result of the fee levels established by FIFRA Lite, we can expect to collect some $28.0 million, or 80 percent of the 1989 levels, under the adjusted active ingredient fees proposed under S. 2050.

Third, the administration's legislation calls for a $750 per product reregistration fee which would apply to all products deemed eligible for reregistration. Under S. 2050, the Administrator of EPA would be given the authority to adjust this fee to a level that would generate at least $4,000,000 during the 4-year period following enactment of the legislation.

Below is a summary of the total revenues that can be expected if the three fee authorities detailed in section 11 of S. 2050 were to be adopted:

[In millions of dollars]

• A 2-year extension on maintenance fees: $15.1 million/year × 2 years	30.2
• A $750 reregistration fee per product	4.0
• AI: $120,000 (food uses); AI: $60,000 (nonfood uses); (80 percent of $35 million collected in 1989!)	28.0
Total:	62.2

The $62.2 million as calculated above, far exceeds the $20 million shortfall stated by EPA officials in testimony presented to Congress last September.

The lack of consistency in EPA's funding estimates illustrates the strong need for a full and complete explanation of expenditures for the registration and reregistration programs, including Fast Track expenditures. We at CPDA believe that Congress should require EPA to provide a clear and detailed accounting of where and how the moneys have been spent since the reregistration program was created under the 1988 FIFRA amendments. It is only when we obtain a full accounting of the program that we can then come up with an accurate cost of the reregistration program and a definite assessment of the shortfall.

In testimony presented before the House Subcommittee on Department Operations and Nutrition last year, Ralph Engel, President of the Chemical Specialties Manufacturers Association (CSMA), recommended that a provision be written into FIFRA which would require EPA to contract with appropriate outside management personnel to conduct a thorough examination of the registration and reregistration process and to make recommendations in a report to Congress as to how to specifically improve program performance and meet the 1997 statutory deadline. CPDA agrees with CSMA and would support the initiation of an outside, independent review of OPP prior to any determination regarding a new request for additional fees.

Like all other Federal agencies, EPA is attempting to "reinvent" government by seeking ways to streamline its operations to do more with less resources, thus creating a more effective and efficient process. As described more fully elsewhere in this

testimony, CPDA has been working with EPA in developing several specific proposals which, we believe, will streamline OPP activities by improving certain efficiencies and eliminating the unnecessary waste of limited Agency resources, both financial and manpower. We at CPDA are pleased to report that the Agency has responded in a very positive manner to many of our recommendations and has expressed a willingness to implement some of our suggestions. Moreover, EPA officials have indicated that some of these changes could be put in place in as short a timeframe as four to 6 months. Among the CPDA recommendations which EPA is now considering include the feasibility of allowing simple registration amendments to be made through notification and improvements in the process for review of acute toxicity data. The changes now under consideration would reduce the employee to manager ratio from its current level of 6 to 1 down to 11 to 1. We at CPDA believe that the results of this streamlining process should be evaluated before determining the necessity for any additional EPA resources.

CPDA does not believe that an extension of maintenance fees to 1999 should be considered until we move closer to these dates and have had the opportunity to see what impact the various streamlining reforms have had on OPP activities. It is premature to address the continuation of maintenance fees at this time. There will be additional FIFRA reauthorizations prior to 1998 at which time this issue can be revisited if Congress deems it necessary. Moreover, although the EPA seeks an extension of maintenance fees for 1998 and 1999, it does not seek an extension of the prohibition of registration fees for the same timeframe. Thus, under the present EPA proposal, registrants would have to pay *both* extended maintenance fees *and* new registration fees.

CPDA remains committed to fulfilling its current statutory obligation of raising $14-million-a-year to fund the reregistration program through September 30, 1997 as provided by FIFRA. However, we strongly believe it is premature to enhance EPA's fee authority until we have had a full review of how and where EPA has allocated industry fees already collected, and until we assess the impact of the Agency's present OPP streamlining initiatives.

Rather than the creation of additional fees, the immediate focus of FIFRA should be on streamlining the reregistration program, improving efficiencies, and eliminating waste and duplication.

CITIZEN SUITS

CPDA opposes the provisions in S. 2050 which would allow a private individual to file civil suit against EPA for failure to enforce the requirements of FIFRA. We at CPDA believe that a citizen suit provision in FIFRA could lead to a proliferation of frivolous lawsuits brought by every activist group seeking the total elimination of pesticides. A provision allowing for citizen suits under FIFRA would keep EPA firmly ensconced in court proceedings and would consume a significant share of Agency resources which would go toward legal and court fees. CPDA does not believe that this is an appropriate use of limited Agency funds and manpower. It would appear that a majority of the House Subcommittee on Department Operations and Nutrition share this sentiment as evident in the panel's rejection of the administration's citizen suit provisions during its July 27, 1994 markup of FIFRA legislation.

REGISTRATION SUNSET

CPDA is opposed to the registration sunset provision contained in S. 2050. This provision would require that active ingredients be reviewed periodically to ensure that they are in conformity with scientific standards. If EPA determines that the pesticide does not meet all applicable requirements, the Agency would be required to initiate cancellation proceedings. We at CPDA believe that this provision would create an unnecessary burden for the Agency and the industry alike. We agree that it is important to address any questions pertaining to the safety and efficacy of registered chemicals as these questions arise. However, we do not believe that it makes sense to engage in a wholesale review of every registered chemical. Much of the information we have on chemicals and the scientific testing methodologies will not change within the relatively short timeframes set forth in the administration's proposal. If EPA has a specific concern pertaining to a chemical, the Agency already has the authority under the data call-in provisions of FIFRA section 3(c)(2)(B) to request the appropriate testing. It is a waste of limited resources to require the resubmission of scientific data which will provide little if any additional new information.

CPDA opposes the registration sunset provisions as presently drafted in S. 2050. We do not believe that it makes sense to engage in the wholesale review of every currently registered chemical. The provisions in the administration's bill would place the enormous burden on registrants to submit potentially vast amounts of data to the Agency, much of which might have, at best, marginal value. While fu-

ture technology promises to provide the tools to generate ever increasing amounts of information, some of this "new" data may not represent a significant change from what we already know about a chemical today.

CPDA recognizes that as science evolves and technology allows for testing at higher levels of sensitivity, so will certain data requirements to support pesticide registrations change over time. To this end, some of the information necessary to maintain pesticide registrations should be updated periodically. However, it is unnecessary to duplicate data which is scientifically valid. Once a pesticide has passed the rigorous requirements of the present reregistration program and the Agency has obtained a complete set of scientifically valid data on a particular product, it is unnecessary to generate a repeat battery of tests to obtain information which has already been accepted and approved by EPA. Instead, further data requirements should focus on specific and significant toxicological concerns over a pesticide should they arise in the future. As such, EPA and industry resources can be more effectively utilized by focusing on specific concerns based on significant evidence of a chemical's possible unreasonable adverse effect on man or the environment.

When the House Subcommittee on Department Operations, Research and Foreign Agriculture conducted a markup of FIFRA legislation (H.R. 3742) during the 102d Congress, it considered a similar provision which would have called upon EPA to perform a "periodic update" of information to support pesticide registrations. At the time, CPDA endorsed a substitute proposal which would have required EPA to review pesticide registrations and to utilize its existing data call-in authority under FIFRA section 3(c)(2)(B) to obtain information deemed necessary for continued support of pesticide registration. The proposal also gave EPA a second option of publishing an order in the FEDERAL REGISTER which would have identified specific data requirements and would have described the significant evidence of unreasonable adverse effects to human health or the environment upon which EPA was basing its request for data. We understand that the intent of the administration's registration renewal or "sunset" provision is to avoid the type of logjam that has occurred with today's reregistration program. CPDA believes that this can be achieved through such an alternative mechanism, as described above, which safeguards against the unnecessary duplication of data.

CANCELLATION

We at CPDA applaud the administration for including a discussion of benefits in its recommendations to revise current cancellation procedures under FIFRA. Specifically, S. 2050 contains a requirement that EPA consider the potential impact of the proposed cancellation action on consumers, retail food prices, production of agricultural commodities, and the agricultural economy. Dr. John D. Graham, Director of Harvard University's Center for Risk Analysis, discussed the importance of benefits during his testimony presented before the House Subcommittee on Department Operations and Nutrition on July 14, 1993. "If farmers are suddenly unable to use pesticides," he stated, "their crop yields (per acre) may decline due to insufficient pest control. Since the costs of producing the same level of output would then be higher, farmers would be forced to charge higher prices for the crops they produce."

"The benefits of lower food prices are not simply financial," said Graham. "[T]hey impact the health of parents and their children. For example, if higher prices for fruits and vegetables cause dietary habits to shift away from these foods, an increase in the risk of cancer, heart disease, and other diet-related diseases can be expected. This outcome is more likely among low-income populations, where price sensitivity is highest and knowledge of the health effects of poor nutrition may be lower."

Dr. Graham further testified that ". . . In some situations, the loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that thrive without the pesticide. For example, although many fungicides have been shown to cause cancer in animals at high doses, some of the toxins produced by fungi, such as aflatoxin, are also known to cause cancer. One of the benefits of pesticides is the human health protection resulting from the destruction of fungi." CPDA shares the sentiments conveyed by Dr. Graham. We believe that any changes to the current cancellation procedures must take into consideration the health and nutritional benefits to be derived from the use of pesticides. We are pleased that the administration has seen fit to include this important provision requiring EPA to consider the benefits of pesticide use before proceeding with a proposed cancellation.

We at CPDA are also pleased that the administration has included in its bill a process whereby EPA would be required to consult with the Secretary of Agriculture before proposing the cancellation of an agricultural use pesticide, and the Secretary of Health & Human Services before initiating cancellation proceedings on a pesticide

registered for public health uses. CPDA also supports the directive contained in S. 2050 which would require EPA to consider changing the classification of a pesticide from general to restricted use as an alternative to cancellation.

Without question, CPDA agrees with the administration that the current cancellation procedures should be streamlined and simplified so as to allow the Agency to move quickly to remove "bad actors" from the marketplace. The experience of the last 15 years has clearly demonstrated that the cancellation process has taken too long, with some products taking more than a decade to remove from the marketplace. However, we feel that in revising the cancellation provisions of FIFRA, caution must be taken to fully protect the due process rights of the registrant and end users who depend on the availability of the chemical in question.

the administration's legislation, S. 2050, would replace the current formal adjudicatory hearing process with a notice-and-comment cancellation process which includes an informal hearing. A registrant would have to request an informal hearing within 21 days of publication of a proposed cancellation order in the FEDERAL REGISTER. Comments on the proposed action would have to be submitted to the Agency within 90 days of publication in the FEDERAL REGISTER. In the absence of a procedure which would provide for an advance notice of proposed rulemaking to be issued prior to a notice of proposed rulemaking, we at CPDA believe that the short time periods set forth in the administration's legislation are inadequate. Under S. 2050, registrants, end-users and other interested parties would have only one opportunity to examine the complex issues inherent in any cancellation action. As such, we would like to suggest longer time periods during which interested parties could request an informal hearing and/or submit comments regarding a proposed cancellation.

Moreover, S. 2050 would allow the EPA Administrator to deny a registrant's request for an informal hearing if "holding a hearing would not be in the public interest." CPDA is concerned that the inclusion of such language could deny a registrant of his due process rights to hear arguments on all sides as they relate to the proposed cancellation of a pesticide. It is imperative that any revisions to the cancellation procedures under FIFRA preserve a mechanism which protects the right of a registrant to defend his product and to present supporting scientific evidence.

While we support the administration's goal of expediting and simplifying current cancellation procedures, we believe that the cancellation provisions of S. 1478, the "Food Quality Protection Act of 1993," introduced by Senators Pryor and Lugar, provide a better alternative for achieving this same objective. In fact, in amending H.R. 1627 during its recent FIFRA markup, the House Subcommittee on Department Operations and Nutrition adopted many provisions which resemble those found in S. 1478.

Like the administration's proposal, S. 1478 would eliminate the current formal adjudicatory hearing requirement for cancellation of pesticide registrations. It would also provide for consultation between EPA, USDA and HHS.

However, unlike the administration's bill, S. 1478 provides for scientific committee peer review of the evidence supporting proposed cancellation, precancellation notice to pesticide registrants that includes a summary of the validated test or other significant evidence upon which the Administrator proposes its action, an advance notice of proposed rulemaking (to be followed by a notice of proposed rulemaking), and the right to seek judicial review of a final cancellation order. CPDA strongly supports all of these provisions contained in S. 1478.

In addition, CPDA believes that it is critically important that registrants be given an opportunity to cross-examine witnesses in any informal hearing adopted as part of the cancellation process so as to build a complete hearing record. As amended by the House Subcommittee on Department Operations and Nutrition on July 27, 1994, H.R. 1627 contains such a provision allowing for cross-examination of witnesses. We at CPDA believe that similar language, if incorporated into the cancellation provisions of S. 1478, would provide appropriate protection of a registrant's due process rights.

SUSPENSION

CPDA is opposed to the suspension provisions contained in S. 2050. the administration's bill seeks to decouple suspension from cancellation procedures. S. 2050 would allow a suspension order to remain in effect for a period of 180 days during which time the EPA Administrator could proceed with initiation of cancellation proceedings. The suspension order would automatically terminate at the end of 180 days if the Administrator does not move forward with a proposed cancellation action. CPDA does not believe that the current suspension provisions of FIFRA need to be revised at this time. Suspension, even if temporary, or for a short time, without an opportunity for a public hearing or a fact-based decisionmaking process,

would effectively destroy the product and its public credibility. In the absence of the initiation of a proposed cancellation action, the 180 day suspension period set forth in S. 2050 is tantamount to placing a chemical in limbo. This provision would merely serve to unnecessarily undermine public confidence in the safety of America's food supply and it would generate misgivings concerning the integrity of EPA's regulatory framework.

CPDA does not believe that EPA's cancellation and suspension authorities should be de-linked. As CPDA stated in testimony delivered before the House Subcommittee on Department Operations and Nutrition on March 19, 1992, "An 'easier' suspension authority would subvert the cancellation process by encouraging EPA to use the 'path of least resistance.'" Suspension authority is an emergency procedure, established under FIFRA, which allows EPA to suspend a product deemed to pose an "imminent hazard" during cancellation proceedings. Current law requires that the Agency issue a proposed cancellation notice before or at the same time it issues a suspension order. This process ensures that suspension actions will not be taken too hastily before the full body of scientific evidence is completely evaluated.

The Clinton proposal to decouple the two authorities could result in the potential misuse of EPA's suspension authority and undermine the science-based cancellation process. We believe that FIFRA reform efforts should focus instead on streamlining the sometimes long and protracted cancellation process, thus ensuring that problem chemicals are removed from the marketplace in an expeditious manner. CPDA believes that the cancellation provisions of S. 1478 can accomplish this objective.

LABEL CALL-IN AND LABEL CHANGES

While CPDA supports efforts to streamline EPA mandated label revisions, we have serious concerns pertaining to the Label Call-in provisions of the administration's bill. Specifically, we strongly oppose the creation of new suspension and recall authorities which would allow the EPA Administrator to take action against any pesticide distributed or sold in violation of the requirements promulgated pursuant to the label call-in provisions of the bill.

Under current FIFRA, only those pesticides that are suspended and canceled can be made subject to a mandatory EPA recall. The language in S. 2050, however, would expand the scope of products which could be subject to a mandatory recall to virtually any pesticide with a label violation—no matter how minor the transgression. A product which bears incorrect labeling through perhaps an unintentional oversight on the part of the registrant certainly cannot be made subject to the same penalties as that which apply to a product suspended and canceled because of health or safety concerns. As such, we strongly urge Members of the subcommittee to reject any legislative language providing for mandatory recall of products under any legislation which seeks to revise EPA labeling procedures.

Similarly, CPDA believes that the label call-in provisions of the administration's bill would significantly relax the circumstances under which the EPA could initiate suspension proceedings. Present FIFRA allows the Agency to issue a suspension notice only if EPA deems that a product poses an "imminent hazard." Again, the administration's legislation makes it much easier for the EPA to suspend a product by removing the criteria that a product poses an "imminent hazard." As with the recall authority contained in S. 2050, the new suspension powers could be used against a number of products for relatively minor, inadvertent label violations. CPDA opposes any efforts to weaken the criteria under which EPA is allowed to proceed with a suspension action.

As mentioned earlier in our testimony, CPDA supports the administration's goal of streamlining label changes and establishing uniform label compliance dates. In particular, CPDA applauds the administration for proposing that one annual date—October 1st—be designated as the date by which registrants must comply with simple mandated label changes aimed at reducing the potential risk associated with the use of a pesticide.

We at CPDA would like to see this proposal broadened to also stipulate that one office within EPA be established to coordinate all mandated label changes for pesticide products. During its markup of FIFRA legislation (H.R. 1627) on July 27, 1994, the House Subcommittee on Department Operations and Nutrition adopted legislative language which establishes a labeling program within the Office of Pesticide Programs (OPP). Section 119 of the subcommittee passed bill requires that all specific label changes mandated by the EPA Administrator be coordinated through this program. The measure requires the EPA Administrator to publish, on October 1st of each year, a list of all label changes mandated for the following year. All affected pesticide products initially released for shipment two or more years after the final announcement would contain the revised label language. We at CPDA

strongly support the label reform language adopted by the House Subcommittee on Department Operations and Nutrition in its markup of FIFRA legislation, H.R. 1627. We urge Members of this Senate subcommittee to include the House provisions on labeling reform when it comes time to vote on a set of amendments to FIFRA.

Many different offices and programs within EPA's Office of Pesticide Programs (OPP) require, at different times, changes on a pesticide product's label. Some of these EPA mandated changes might be to change an ingredient, an inert, or a use. Sometimes a label might need to reflect some new set of directions or warnings about use or specific health and safety instructions. Sometimes the Agency may require that the registrant reshape the label or reduce its size, or place new instructions for proper disposal of the container on the label.

Specific programs also address specific needs to change the label, such as the Endangered Species Program, container rinsing proposals from the new FIFRA "Lite" requirements, and other programs. In addition, label changes may be requested from the Air and Water Divisions of EPA to conform with the Clean Air and Water Acts. Many different offices and programs require the registrant to make changes on the label, *but no one part of the Agency coordinates appropriate label changes.* These various programs do not know what the other parts of the Agency are doing about label changes.

A company frequently makes a label change in response to an EPA office's request, and prints thousands of new labels, only to find that another EPA office, program or division is requiring additional changes. Many companies print up new labels just in time to throw them in the trash. It can be an expensive, time-consuming and frustrating experience and means money and jobs for many small businesses who are fighting to compete in a tough market.

To give you some idea of the magnitude of this problem, a random sampling of CPDA companies indicates that, on average, they spent in excess of $808,600 over the past 6 years on labels which were ultimately discarded. For these companies, this translates to approximately 5,600 wasted man-hours and represented more than 1,613,000 labels which never saw the light of day. When one extrapolates these figures to the entire industry, it becomes very apparent that a problem exists which needs to be addressed quickly.

A number of CPDA member companies cite a definite lack of coordination between product managers, Label Improvement Program (LIP) personnel, and other Agency staff in formulating label requirements. Representatives of one CPDA member company, for example, report that they have been required to write the Confidential Statement of Formula (CSF) for the *same* pesticide in different ways for different EPA personnel. This same company also notes that it has received conflicting instructions from various Agency personnel regarding the wording of the Precautionary Statements found on phenoxy labeling.

Other OPP programs which affect reregistration, the container disposal program, the regulation of inerts, farm worker protection standards, certification and training requirements, and product reclassification will certainly have an impact on the fate of present labels or the re-labeling of existing stocks.

One small-sized formulator of lawn and garden products responds that it seeks to reduce waste in its labeling operations by printing small quantities of labels on a more frequent basis. However, the company also notes that it is then faced with the disadvantage of having to pay a significantly higher unit cost per label. In these troubled economic times, a small business cannot afford to incur such needless and unnecessary costs.

In an effort to improve the way in which the Agency handles label revisions, we at CPDA suggest that one office in OPP, within the Registration Department, should coordinate all label changes from all programs, all product managers, and all divisions so that there is no confusion about the necessary changes needed to comply with EPA's mandates. At present, many different offices and programs require the registrant to make changes on the label, but *no one part of the Agency coordinates appropriate label changes.*

Second, one date each year should be selected for all EPA-mandated label changes. We support October 1st, the date set forth in S. 2050, as a good date because it represents the end of the growing season as well as the beginning of a new fiscal year. All label changes could be effective on this date, so that companies can start production in the fourth quarter for the following Spring's use. We would like to point out that this date is also found in the labeling reform provisions of H.R. 1627, as amended by the House Subcommittee on Department Operations and Nutrition.

Third, companies need enough lead time to implement the Agency's requirements for both new product labeling and for the re-labeling of existing stocks. We support

the timeframes set forth in H.R. 1627, as amended in subcommittee, whereby all affected pesticide products initially released for shipment two or more years after the final announcement would be required to bear the revised label language.

The Agency has already taken steps to improve its labeling process by assembling a team of six staffers to work on label improvement. CPDA would like to recommend that this process be taken one step further and that Congress adopt legislation to establish a formal office to handle labeling streamlining so that EPA receives the appropriate funding and resources to effectively implement a label improvement program.

REDUCED RISK PESTICIDES

We at CPDA support efforts to promote the safe use of pesticides. However, we have several concerns pertaining to the administration's legislation which would establish a 180-day priority review of pesticide registrations deemed "reduced risk." Specifically, we believe that EPA's already limited resources would be severely strained under the registration priority schedule set forth in S. 2050. The registration of many effective and beneficial products would be delayed if EPA resources were to be focused primarily on chemicals meeting the criteria of "reduced risk." The registration of specialized, niche-oriented minor use pesticides could suffer the most. The economics of developing low volume minor uses is already cost prohibitive due to expensive testing requirements. It takes about $50 million and five to 10 years to bring a pesticide product onto the market. Delays in the registration of minor use pesticides in deference to so-called "reduced risk" chemicals would further erode the profitability of many minor uses and take away any incentive to develop these chemicals.

Moreover, we at CPDA believe that the designation of a new product as a "reduced risk" pesticide could misguide the public's perception of older chemicals, many of which have been used for years without significant harm to man or the environment. EPA's role is to ensure that all pesticide registrations meet the same standard under current FIFRA of posing no unreasonable adverse effects to human health or the environment. If EPA is allowed to make a public judgment that one chemical is safer than another, the Agency would indirectly play a role in influencing marketplace trends. We at CPDA do not believe that EPA should be involved in shaping the market by favoring one product over another.

Many older pesticides should qualify for designation as reduced risk pesticides. Some products are being developed that significantly reduce the use of active ingredient, with reduction of 25 to 50 percent. Some products shift to new delivery systems, while others change their packaging to reduce exposure. Products in water soluble bags reduce exposure to handlers and applicators. Each of these types of "old" chemicals actually reduces risk and should be considered "reduced risk pesticides."

In addition, the elimination of older pesticides from the marketplace could have a negative impact on Integrated Pest Management as farmers are left with fewer tools to combat pests effectively. A broad, diverse product line which includes the continued availability of older chemicals must be preserved so that farmers may engage in IPM practices as a means of preventing the buildup of resistance to pesticides.

EXPORTS

We at CPDA do not believe that the laws governing the export of pesticides needs to be changed at this time. Indeed, at a time when the United States is seeking to promote its trading status in the global markets, the implementation of unnecessary export restrictions could have a negative impact on American jobs.

While we support the administration's goals of ensuring that chemicals banned for health or safety reasons do not make their way onto foods imported into the United States from foreign countries, CPDA believes that the Agency has already embarked on a number of initiatives aimed at improving the regulation of pesticide exports. For example, the EPA is working with OECD member countries on several pilot projects aimed at achieving uniformity in international pesticide regulation. In addition, on January 1, 1992, the Food and Agricultural Organization (FAO) and United Nations Environment Programme (UNEP) jointly implemented the international program on Prior Informed Consent (PIC). The PIC program embraces many of the concepts set forth in the export provisions of S. 2050 by allowing participating nations to receive information about pesticide exports that have been banned domestically for health or safety reasons. Participating nations would have the opportunity to prohibit these chemicals from moving across their borders.

In other activities, the United States has negotiated a set of sanitary and phytosanitary standards under NAFTA and the Uruguay Round trade discussion

aimed at protecting the integrity of foodstuffs entering our country. The focus of these talks has been to harmonize standards, facilitate compliance, and eliminate any unnecessary nontariff barriers to trade.

In the last 3 years, considerable progress has been made concerning the increased regulation of pesticide exports. We at CPDA oppose the inclusion of section 3 of S. 2050, and request that it be deleted.

Section 3(b)(4) states that "no person may export a pesticide to a foreign country if any ingredient of the pesticide has not been and is not the subject of any registrations under section 3 . . ." We interpret this language to mean that unregistered pesticides can be exported as long as the active ingredient and/or end use product has been registered by another entity. For example, company A registers product Y and sells it in the United States and abroad. Formulator B buys product Y from company A, but only exports the product (not for use in the United States). Consequently, unregistered products should not be labeled as unsafe pesticides.

There are numerous reasons why a product may not be registered with EPA. These include, but are not limited to:

- The producer does not want to subject himself to current FIFRA data compensation liabilities. With the threat of millions of dollars in data compensation payments, many would-be competitors back away from the U.S. market.
- The producer is concerned with the current wave of product liability litigation in the United States and does not want to fall victim to potential lawsuit.
- The producer does not feel the costs involved in generating EPA data can be justified by potential United States sales.
- Many foreign pesticide manufacturers have made arrangements with large multi-national firms to compete in the U.S. market. Thus, they will not allow their products to be registered in the United States and will only sell manufacturer goods which are to be formulated and exported.
- Different analytical methods used by countries in measuring active ingredients.
- Crops are not grown in the United States or the particular pests do not exist domestically.

Thus, this legislation could have great impact on many companies. For example, one of our companies sells natural pyrethrins in the United States and Canada, via an EPA registered pesticide, according to an EPA accepted AOAC method of analysis. These products can be sold in the United States and Canada because they conform to standards accepted in these countries, but cannot be sold anywhere else in the world with an EPA registration, its EPA label or its AOAC method of analysis. The exact same product, with the identical six esters, is not analytically measured by the same standard. The rest of the world abides by the analytical method developed and approved by the Pyrethrin Board of Kenya (PBK). The internationally accepted PBK creates a differential of 10 percent in favor of PBK. For example, a 100 percent concentration in the United States might be 10 ounces, but the identical concentrate in Kenya would be recorded as 11 ounces. A standard 20 percent pyrethrin extract measures 22.11 percent in Kenya, despite the fact that they are an identical product.

For 60 years, a conflict over analytical measurement has existed between the United States and Kenya, and for almost 35 years, this company has exported a pyrethrin product, identical to its United States counterpart, to the rest of the world with a label approved and accepted by PBK and the world.

Because of the differences in analytical methods, these products are *NOT* registered in the United States or Canada. Provisions of S. 2050, requiring the export of only EPA registered pesticides, would prevent the sale of these products overseas. If the company could not export these products, we feel confident that other companies in the United Kingdom, France, West Germany and Australia would immediately step forward to fill the void, further reducing American export opportunities.

To register this identical pyrethrin product in the U.S., according to EPA's accepted AOAC analytical methods, the concentrations would have to be labeled 22.11 percent concentrate (not 20 percent). Since there would be a perceived "difference" in concentration, the EPA would probably treat this product as a "new" product, requiring a complete set of data based on the testing of this concentrate. It would not be a "me-too" registration. Consequently, it could take between two and 3 years or more to register this "new" product, during which time period the product could not be sold on the international market. The cost of this registration effort, with product chemistry testing, and other testing, could run between $75,000 to $100,000.

Although S. 2050 supposedly is designed for agricultural uses (*i.e.*, food, feed or fiber crops), it groups all pesticides together, including nonagricultural products such as sanitizers, disinfectants, cleaners, etc. Any pesticide export section, by defi-

nition, should be restricted to agricultural food uses such as those products used on food, feed or fiber crops.

We at CPDA strongly oppose the establishment of "fees on pesticide registrants" for the purpose of covering the costs of this EPA program.

First, at a time when, as a Nation, we are attempting to create more jobs here at home, while stimulating exports abroad, it is ludicrous to tax our own exports, thereby driving up their costs and making them less desirable.

Second, the legislation gives the Agency the power "to assess fees on pesticide registrants." Thus, it broadly applies to *all* registrants, including those that don't export. Why should a small American formulator who does not export be forced to subsidize the exports of a larger, international company that is exporting? It is unfair to subject any company that does not export pesticides to the same fees that apply to those companies that do export.

Finally, we do not support the creation of a $4-million technical assistance program. If the Agency is looking for a home for $4 million, it can "reinvest" it in the registration or reregistration program.

THE ADMINISTRATION'S AMENDMENTS TO THE FEDERAL FOOD, DRUG AND COSMETIC ACT

We at CPDA would now like to address S. 2084, the Pesticide Reform Act of 1994, introduced by Senator Edward M. Kennedy (D–MA) as part of the Clinton administration's key proposals to amend the Federal Food, Drug and Cosmetic Act (FFDCA). This legislation raises many concerns by: (1) creating unnecessary and duplicative EPA regulations; (2) stimulating significant additional costs; (3) increasing the burden on Agency resources; (4) creating a "new" Delaney clause; (5) delaying the reregistration process by superimposing a new tolerance review process; (6) encouraging the worst case assumptions on exposure data and pesticide residues on food; and, (7) containing no uniform national tolerances.

THE DELANEY CLAUSE AND THE NFPA PETITION

Over the past several years EPA has publicly stated that without legislative intervention, it is bound to implement the court decree from *Les* v. *Reilly*, which interprets the Delaney clause under a zero risk standard. Under current EPA policy, this could require EPA to revoke large numbers of food tolerances subject to the Delaney clause and could result in a disturbance of the Nation's food supply. In regards to the court mandate, EPA has stated that the Ninth Circuit Decision "does not reflect good public policy or good science policy" and that the pesticides subject to Delaney "pose only a negligible risk to public health."

Yet EPA has failed to implement administrative changes which would mitigate the adverse effect of Delaney on agriculture and the Nation's food supply. Despite 2 years of deliberation, the Agency has failed to respond to the National Food Processors Association (NFPA) administrative petition to decouple 408 tolerances from 409 tolerances. Because the Delaney clause only applies to 409 tolerances, a decoupling of 409 and 408 tolerances would leave many safe and beneficial pesticide raw food uses and registrations undisturbed. However, under current Agency policy a 408 tolerance and its registration may be revoked if the 409 tolerance is revoked and the pesticide concentrates in processed food.

The decoupling of 408 and 409 tolerances represents the exercise of sound scientific and legal practice by EPA and could be accomplished administratively without legislative intervention.

Instead, EPA has declined to release a public statement on the NFPA petition and continues to revoke, in a piecemeal fashion, 409 tolerances. In all likelihood, the reluctance of EPA to fix Delaney from a regulatory perspective, stems from its desire to gain political pressure for passing its legislative agenda.

Although CPDA believes the Delaney clause's "zero-risk standard is no longer scientifically justified and is virtually impossible to achieve, we do not believe the administration's proposed health based tolerance standards, which ignore a benefits evaluation, will satisfactorily solve the Delaney problem. The FFDCA can be amended in a simple manner to reinstate the flexible concept of "negligible risk" (a concept which EPA has long supported) when setting permissible tolerances for pesticides in processed food. A strict health based standard, as proposed by the Administration, will likely cause the revocation of tolerances which do not pose a *real* health threat to the American public and will likely cause a disruption of the Nation's food supply.

We at CPDA strongly support S. 1478, the Food Quality Protection Act of 1993. The bill would create a single negligible risk standard for tolerances for pesticide residues in raw commodities and processed food. EPA would be responsible for defining negligible risk in light of evolving science, taking into account different routes of exposure to a pesticide and sensitivities of population subgroups. EPA would be required, where reliable data are available, to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

These provisions of S. 1478 resemble the tolerance setting provisions of H.R. 1627, as it was amended by the House Subcommittee on Department Operations and Nutrition during its recent markup of pesticide legislation.

BACKGROUND ON THE DELANEY CLAUSE

The U.S. Court of Appeals for the Ninth Circuit ruled in *Les* v. *Reilly* on July 8, 1993 that section 409 of the Federal Food, Drug, and Cosmetic Act, the "Delaney clause," requires EPA to apply a "zero-risk" standard for carcinogens when setting permissible tolerances for pesticides in processed food.

The *Les* ruling could have a disastrous effect on the abundance and safety of our nation's food supply and the agrichemical industry as a whole. The decision could lead to the cancellation of thirty five different pesticides, which comprise more than 10 percent of the basic pesticide ingredients used in agriculture, and hundreds of different uses which were previously approved by EPA.

In 1958 Congress passed the Delaney clause, which states in part that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." EPA had previously construed this clause using a *de minimis* standard for pesticide residues in processed food.

Under the *de minimis* standard a tolerance was granted if the human dietary risk from a pesticide was so remote that the threat of contracting cancer was "at most negligible." The Ninth Circuit, however, has interpreted the Delaney language "found to induce cancer" to mean no traces of carcinogens in residues for processed food, regardless of how borderline the response in test animals or how marginal the risk may be to consumers.

The "zero risk" standard is simply unworkable for establishing reasonable risk evaluation. When Delaney was promulgated, almost thirty 5 years ago, the usual scientific testing standards measured in the parts per million. Scientific detection standards now measure in the parts per trillion and greater, resulting in the detection of carcinogens which present at the most a remote and negligible threat to the public.

A mass revocation of these pesticides will likely lead to fruit, grain, and vegetable price increases and a decline in the quality of our food. A subsequent reduction in the consumption of these products by our citizens could lead to the erosion of our health and the nutritional integrity of our diets. The American Cancer Society strongly maintains that Americans need to double their *present* consumption of fruits, vegetables, and fiber to reduce the incidence of various types of cancers. Implementation of a "zero-risk" Delaney clause would therefore likely *increase* the incidence of cancer across the country.

The EPA has a vast wealth of resources, personnel, and scientific knowledge it uses to draft pesticide policy. As a Federal agency it has the regulatory discretion to interpret statutes in order to effectuate this policy. EPA has long determined that a "negligible risk" standard most effectively protects the health of the American consumer and maintains the abundance of our nation's food supply.

TOLERANCE SETTING

CPDA strongly objects to the administration's proposal for a health-based safety standard for setting tolerances which does not take into consideration benefits. A "reasonable certainty of no harm to consumers of food" standard which the Administration proposes is no different in protection than existing law, which bars residues which are "unsafe" and only allows levels which are "necessary to protect the public health." This new standard, however, does not take into account the wealth of economic and public health benefits pesticides provide consumers.

The administration plan requires the consideration of other pesticide risks when setting tolerances. For example, drinking water or nondietary exposures, risk of other chemicals causing the same effect and risk to potentially sensitive subpopulations would be considered. CPDA is opposed to this approach because it is purely speculative as to when and how often the combination of these elements will affect pesticide exposure in the food supply. We at CPDA believe that it is impossible to derive a true, scientific measurement of the potential risks caused by such variables.

An approach which calls for the consideration of these fluctuating factors would inflate the actual level of risk associated with the presence of pesticide residues in foods.

The administration plan also requires EPA to assume high food consumption rates at maximum residue levels to determine the safety factor for setting tolerances. The provisions of S. 1478 (which resemble those contained in the amended version of H.R. 1627) are preferable, for these alternative initiatives take a more realistic view of setting tolerances. EPA would be required under both S. 1478 and H.R. 1627 to calculate the dietary risk posed to food consumers by a pesticide on the basis of the percent of food *actually treated* with the pesticide and the *actual* residue levels of the pesticide that occur in food.

The administration is very committed to maintaining and enhancing food safety for infants and children. Its proposals for tolerance setting respond directly to recommendations contained in the NAS report, "Pesticides in the Diets of Infants and Children," that EPA consider unique aspects of children's diets and nondietary sources of pesticide exposure.

CPDA fully supports comprehensive USDA funding to collect improved food consumption data for children. We also believe that foods commonly consumed by children should be a priority in residue monitoring. It should be noted, however, that the NAS study indicated there are *no identifiable problems* with pesticide use in children's food, but that more in depth studies need to be taken to fully understand whether this conclusion is correct.

It is the administration's position that where children's data is not available, EPA will employ "conservative estimates," unless the registrant can provide more accurate data. It is important that tolerances which are soundly justified by scientific evidence for the general population are not too greatly skewed by unproven subpopulation concerns. In addition, it is important that EPA take a close and reserved look at considering nonfood exposures when setting food tolerances. A reliable correlation between the two may be difficult to implement on a consistent basis.

CPDA is opposed to legislation which, in the absence of adequate data on children's food consumption patterns, allows EPA to utilize a "worst case" scenario under which assumptions of maximum dietary exposure are made. CPDA supports the more desirable alternative as set forth in the provisions of both S. 1478 and the amended version of H.R. 1627 which would require EPA to establish tolerances on the basis of the percent of food actually treated with the pesticide and the actual residue levels of the pesticide that occur in food.

TIMELY REVIEW AND ACTION ON EXISTING TOLERANCES TO ENSURE COMPLIANCE WITH THE NEW SAFETY STANDARD

A key provision in the administration's proposal is a fundamental change in the approach to regulating the safety of pesticides in the food supply: a self-executing statutory requirement that forces all tolerances to meet the new safety standard by fixed deadlines. The Administration proposes that the review of all tolerances be completed within 7 years after enactment of a legislative reform package, and that pesticide tolerances that now appear not to satisfy the safety standard be subject to special "fast track" review procedures.

The Agency presently has the means to review a pesticide tolerance if a problem with the pesticide's use is apparent. CPDA does not believe the wholesale review of every tolerance is a wise or appropriate allocation of EPA's limited resources. Only if a legitimate concern exists, should a tolerance be reviewed. CPDA is opposed to immediate cancellation provisions for those tolerances which have not met the statutory deadline of 7 years but have not shown to be a bona fide health concern. A review provision must exist for situations in which the manufacturer has not met the burden in 7 years but no real health concerns have been shown to exist.

TIME-LIMITED TRANSITIONAL TOLERANCES

Under the administration's new tolerance review, however, EPA would have the authority to maintain tolerances for a nonrenewable period of no more than 5 years for a chemical that does not satisfy the strict health standard if justified to maintain direct health benefits to consumers or to avoid significant disruption in the food supply. EPA should consult with the U.S. Department of Agriculture (USDA) concerning any possible disruption in the food supply.

If a tolerance can justifiably be allowed to be used for 5 years because its benefits clearly outweigh its risks, it should be permanently established at that level until a suitable substitute is registered. The Clinton plan provides only for a 10-year period for these tolerances to remain on the market. However, CPDA believes that no time limits should apply to those tolerances which, if revoked, would create a sig-

nificant disruption in the food supply. The administration's 5-year tolerance extension is underlies the fundamental rationale that all benefits must be considered when setting tolerances or registering pesticides. How can the Administration ignore benefits and believe they are worth considering in some situations and for limited time periods, but not for all tolerances and all registrations?

INERTS

The administration's legislation to amend FFDCA, S. 2084, would revise the definition of a pesticide chemical to include inerts. A similar provision is contained in S. 1478. We at CPDA are strongly opposed to any legislative language which would expand the definition of a pesticide to include inerts. In fact, when the House Subcommittee on Department Operations and Nutrition adopted its amended version of H.R. 1627, it specifically rejected a provision which would have included inerts in the definition of a pesticide. We at CPDA urge this Senate subcommittee to take a similar position in opposing any legislation which would incorporate inerts into the definition of a pesticide.

Under an amendment to section 201 (a)(q)(1), the definition of a pesticide chemical is changed to also include *all* inert ingredients. The term "inert" should be deleted so that we can return to the original definition of a pesticide chemical. Under this definition, future residue testing could include testing for all inert ingredients, regardless of their level of toxicity.

All present residue testing for the current reregistration of particular crops and uses could be invalidated for hundreds of pesticides and thousands of uses, many of which are minor uses. Present residue testing studies for key metabolics (not inerts) costs an average of about $150,000 per crop use per product. By adding all inerts, the cost could jump $50,000 to $100,000 for each crop use for each product.

EPA has an extensive inerts program in which the Agency can require testing on any or all inerts, and has established a priority program to examine inerts of toxicological concern. In essence, EPA has the present authority to require any testing of inerts it needs. By lumping all inerts together, there is no distinction between the four categories of inerts, and no emphasis placed on inerts of toxicological concern.

By driving up the cost of residue testing on all crop uses, we further jeopardize minor uses, unnecessarily drive up the price of pesticide products to the American farmer, and place the American pesticide industry at a serious comparative disadvantage in a competitive world marketplace.

We also place a massive burden on EPA resources to require review and decision-making on all inerts, thus placing the Agency in an inflexible straitjacket that unnecessarily drains money and manpower from already declining resources.

NATIONAL UNIFORMITY OF TOLERANCES

We at CPDA strongly support section 408(l) of S. 1478 because it establishes a national uniform system of tolerances. Subsection (4) clearly states that "no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residues in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination." Similar language was adopted by the House Subcommittee on Department Operations and Nutrition in its recent markup of H.R. 1627.

THE NEED FOR IMPROVEMENTS IN EPA'S REGISTRATION PROGRAM

We cannot expect to promote interstate commerce in agricultural commodities, or the processing, storing or transporting of a food, if we allow States or local political subdivisions to impose their own tolerances for a pesticide chemical residue. Otherwise, we could find ourselves in the unacceptable position of allowing States or local governments to create barriers to interstate commerce, thus returning us to the pre-U.S. Constitution days of the Articles of Confederation period in American history. Rather than returning to the 18th century, we need to plan for the 21st century by adopting the national uniformity provisions contained in both S. 1478 and the amended version of H.R. 1627. Unfortunately, S. 2084 contains no similar language.

We believe that EPA should channel its resources on implementing procedures which would streamline and expedite the registration process for *all* chemicals. Over the past several months, CPDA has worked closely with the Agency in developing a set of proposals which would help streamline the OPP registration program. Our association has submitted to EPA a detailed proposal which makes recommendations pertaining to the coordination and streamlining of pesticide labeling, uniform-

ity in the review of data requirements, the expansion of the Agency's notification process to allow for registrant certification of simple registration amendments, the need to fix "fast track," and the creation of single registrations for identical products in different packaging. We at CPDA believe that reform in these areas will facilitate the availability of safe, beneficial and effective products and, at the same time, will remove many of the barriers which now exist in bringing a product onto the market.

CPDA would like to point out that some of these initiatives have been incorporated into the package of amendments adopted by the House Subcommittee on Department Operations and Nutrition in its recent markup of pesticide legislation, H.R. 1627. CPDA would like to take this opportunity to detail several of the initiatives which we have proposed to EPA.

SINGLE REGISTRATIONS FOR IDENTICAL FORMULATIONS IN WATER SOLUBLE PACKAGING

For many years the Agency has allowed different products of identical formulation to be registered under one "master label" at the Agency. Administratively, this policy made sense, for these products were the same pesticide, but were marketed in different package sizes.

Recently, however, the Agency has required product amended to be sold in different packaging or sizes to maintain its own separate registration. For example, products packaged in water soluble packaging and rodenticides packaged in closed "place pack" containers were required to maintain their own registrations, separate from the registration already established for the exact same pesticide product.

Unfortunately, this policy has dissuaded companies from marketing new products with safer packaging because of the high State and Federal fees for maintaining a registration. The Agency's emphasis on safer pesticides, reduced levels of user exposure and decreased container waste, should however, make these technologies leading candidates for promotion at the Agency.

To streamline the process for registering products with the same active ingredients and same formulation, but with different packaging, so as to not require a separate registration, CPDA urged the Agency to establish procedures for registrants to notify the Agency about changes in packaging.

The main purpose of this expanded notification process is to avoid the unnecessary duplication of the registration process, to utilize the master label concept with the ability to split the label, and to allow the Agency to utilize its limited financial resources and declining manpower pool on other, more risk related issues.

The unnecessary duplication of the registration process discourages innovative ideas in packaging, delays market entry, and increases fees at the Federal and State levels. By promoting new packaging, such as water soluble bags, it is possible to promote a closed system approach that enhances safety by reducing mixer loader exposure for agriculture products. It also complements the Agency's effort to reduce the number of nonrecyclable pesticide containers and at the same time reduce the unnecessary use of hazardous landfills. In addition, cereal rodenticides which are sold in place packs and wax block and rodenticides which are sold precut reduce exposure to consumers and users.

Existing EPA policy does not encourage or provide incentives for safer, more efficient packaging. In fact, it discourages new innovations in packaging by requiring separate registrations, delayed market entry, and increased fees at the Federal and State levels.

Although EPA has consistently held a policy of promoting pesticides with reduced risk or "safer pesticides," and has recently promulgated new container regulations to reduce the number of pesticide containers and reduce exposure, it has not taken similar initiatives for water soluble packaging.

Utilizing water soluble packaging to load crop protection chemicals into spray tanks will result in a "closed" system that will significantly reduce mixer-loader exposure as opposed to the "open-pour" methods.

Across the board, it also reduces container disposal, solid waste collection, and utilization of land fills. By shifting from a liquid to a dry powder, with a water soluble bag, there is an inherent increase in safety concerning accidents, spillage, and a possible reduction in groundwater contamination. It is far easier to cleanup a breakage or spill if the product is in a dry form, compared to a liquid form.

Although rodenticide registrants are utilizing the same active ingredient, same formulation, they are attempting to develop innovative packaging concepts to meet consumer demands. The Agency has been requiring separate registrations for cereal bait formulations packaged in "bulk containers" or in small packs, commonly known as "place packs." The application directions differ for bulk bait, which requires

placement in terms of ounces, whereas those for "place packs" are described by the number of packs.

In another example, one formulation of a paraffin based "all-weather" rodenticide block bait, which is scored to be broken by the user is commonly required to have a separate registration number from a product with the same formulation which is sold precut into pieces. The only difference between the products is that the application directions for the first product include instructions for breaking the bait. If the Agency feels that different application directions are needed to promote consumer health and safety, registrants do not oppose putting different directions on different sizes. But many insecticides and many consumer products provide different directions for users without requiring separate registrations. In fact it is common place for Agency registered products to have one registration number for different sized packages of the same products.

Current regulations require the registrant to seek a new separate registration for each product utilizing water soluble packaging. Even if the registrant is utilizing the same active ingredient, the same formulation, with the same level of toxicity, the Agency is arguing that two package types cannot utilize the same EPA registration number if the use directions are different. It is important to note the site and dosage rates are usually the same, only the mixing instructions are different. For example, rather than require one quarter pound per acre, the registrant is requiring X number of packets per acre or X number of packets for Y number of acres. For crop protection chemical, the registrant is attempting to restate the use directions by shifting the mixing instructions, not the site or dosage rate.

By requiring a separate registration for each "new" water soluble packaging product or different rodenticide size/shape, the Agency is delaying market entry by one to 2 years, and forcing registrants to go through the costly and timely registration process.

The Agency is also utilizing its resources, both financial and manpower, to review and approve these additional registrations at a time of declining budgets and manpower allotments. By streamlining existing procedures, the Agency could save enormous resources, while preventing the unnecessary duplication of registrations.

Each registrant must pay additional fees at the Federal and State levels for each "new" product. At the Federal level, it requires $1,300 for each product in additional maintenance fees. If also registered in 50 States, it can cost up to $5,500 in State fees for each product.

EPA has recently notified CPDA that it intends to issue a PR Notice which will allow single registrations for identical products in water soluble packaging. CPDA is pleased that the Agency is taking this action. We believe that this action will help reduce the disposal of containers, reduce exposure to mixer-loader employees, reduce the amount of Agency time spent on reviewing these registration applications, and save pesticide registrants as much as $50,000 to $100,000.

THE NEED TO FIX "FAST TRACK"

For almost 6 years, the EPA has been implementing the provisions of the 1988 FIFRA "Lite" amendments, but has not been able to clear the backlogs that exist in the registration division. This backlog especially impacts "Fast Track" or "expedited review" products, despite Congressional authorization for up to $2 million per year of reregistration maintenance fees to be used to implement "fast track."

On the front-end review process, the Agency has done an adequate job of reviewing the original documents and determining if they are in order and complete. This initial review has usually been completed in 45-days. The second phase—requiring 90 days—provides for the finalization and approval or rejection of an "expedited review" application. It appears that "an expedited review" product gets no special handling in this second phase. It seems simply to go to the bottom of the pile.

The *"ninety day"* second phase has taken anywhere from 6 to 18 months, with some isolated examples that required more than 2 years. The Agency has not moved quickly enough to solve these "fast track" problems. Some simple label changes, such as alternative brand names or the addition of alternate sources of supply to a confidential statement of formula, that take 15 minutes to review, instead, take 6 months to filter through the process. Many label changes need only prompt responses, without delegation of responsibility. We see little evidence that the Agency has moved quickly enough to put the appropriate personnel in place to handle this workload.

We believe that existing resources within EPA's OPP should be utilized to address "expedited review" backlogs. Assignments of specific personnel to handle expedited review should be made. For example, one person on a product manager's team should be designated for expedited review. When he or she is caught up, then, he

or she could return to other team assignments. The amount of time needed would vary from team to team, depending on the number of cases to be handled.

Under present handling of "me-too" applications or simple amendments, each of these expedited review applications is placed in one stack with all other applications. There should be two stacks—one for expedited review, and another for other applications.

Many "me-too" applications simply take too long to review. Frequently, each application goes through a seven step review process, each of which is time consuming. Rather than a seven step process, a first level reviewer should be given the authority to complete the process.

To facilitate the quick identification of expedited review applications, the applications should be more easily recognized by color coding the application.

If the Agency fails to comply with the 90-day deadline, for whatever reason, it should provide the registrant with an up-date, and an expected timetable for completion. Without this type of status report, registrants cannot make normal business decisions or marketing plans.

We at CPDA believe that section 112 of H.R. 1627, entitled "Requirements for Registration of Substantially Similar or Identical Pesticides and Antimicrobial Products," addresses many of the present shortcomings of the "Fast Track" system. We at CPDA would strongly urge this Senate subcommittee to give some serious consideration to the merits of legislative language contained in section 112 of H.R. 1627.

THE NEED TO EXPAND THE AGENCY'S NOTIFICATION PROCESS

In order to reduce the backlog in registration applications at the Agency, we at CPDA believe that the notification process should be broadened in order to expedite common product amendments which do not involve the introduction or increase in risk. We have recommended that the Agency establish a certification process by which a registrant could certify that its registration application meets the Agency's requirements and regulations for registration. The following are just a few examples of the types of registration amendments which could be accomplished through notification:

- New areas (site and pest) of use within the same category not requiring additional data;
- Use precautions related solely to a registrant's liability for efficacy, crop damage, or compatibility;
- nonsubstantive label changes which do not effect the safety or manner in which the consumer understands how to use the product;
- EPA initiated label changes and environmental marketing descriptions subject to FTC restrictions; and,
- Changes in inert ingredients.

THE NEED TO ACHIEVE A MORE EFFECTIVE REVIEW OF DATA

We at CPDA believe that the Agency can streamline and improve data review by adopting the following suggestions:

- Notification or self-certification of acute toxicity studies, except for inhalation and dermal sensitization;
- Review and approval of data protocols in a timely manner;
- Early warning system for registrants; dialog on issues as they arise; early consultation on PR Notices;
- Consistent review of toxicity studies; and,
- EPA's precautionary labeling reviewers need to follow the stated Agency positions in the toxicology rejection rate criteria document.

At a time of limited Agency financial resources and declining manpower, it is important that the Agency do more with less, while not impairing risk or adversely affecting man and the environment. We at CPDA believe that the recommendations set forth here in our testimony will help the Agency achieve this goal.

PUBLIC HEALTH PESTICIDES

In its provisions on pesticide minor uses, S. 2050 includes a provision, wholly supported by CPDA, which recognizes the need to protect the continued availability of public health pesticides. As such, the administration's legislation would direct the Department of Health and Human Services and EPA to collaborate in identifying critical public health minor uses that might otherwise be lost, and to arrange for

necessary data support, with HHS adopting a role similar to that filled by USDA's IR–4 Program for agricultural minor uses. S. 2050 authorizes appropriations of $12,000,000 for fiscal year 1993 to be used by the Secretary of Health and Human Services in providing support for the required studies needed to continue the registration of public health pesticides.

CPDA applauds the public health pesticide provisions contained in S. 2050. In supporting the administration's provisions on public health pesticides, we would also recommend that the subcommittee incorporate into any FIFRA amendment package the provisions of H.R. 1867, introduced by Representatives Dooley and Herger during this 103d Congress. CPDA would like to point out that the language of H.R. 1867 and the administration's provisions on public health pesticides were adopted by the House Subcommittee on Department Operations and Nutrition in amending H.R. 1627 during its recent FIFRA markup.

Titled the "Public Health Pesticides Protection Act of 1993," H.R. 1867 embodies many of the concepts set forth in the public health provisions of the administration's bill. We believe that H.R. 1867 affords appropriate protection for many of these low volume products which are critical to preserving the public health. The Dooley-Herger bill ensures that EPA establish guidelines that take into consideration the need for and benefits of public health pesticides used to combat disease-carrying insects and pests and to ensure that these products are not lost in the reregistration process due to economic reasons alone.

The Dooley-Herger bill contains provisions which would:

- Define public health pesticide uses in the context of minor uses;
- Create a separate class of pesticide registration for public health pesticides with a risk-benefit balance, which is separate from that utilized for agricultural pesticides;
- Require that the EPA Administrator take into consideration "the differences in concept and usage" between agricultural, nonagricultural, and public health pesticides;
- Require consultation by the EPA Administrator with the Secretary of Health and Human Services on pesticides for public health uses, similar to the existing consultation between EPA and USDA; and,
- Expedite the registration of products necessary for the protection of public health.

On April 23, 1991, Dr. William Hazeltine, Manager-Environmentalist of the Butte County Mosquito Abatement District in California, appeared before Members of the House Subcommittee on Department Operation's Research and Foreign Agriculture. More recently, he appeared before the House Subcommittee on Department Operations and Nutrition on June 8, 1993 during FIFRA oversight hearings. During each of his Congressional appearances, Dr. Hazeltine eloquently drew attention to the need to create a public health provision in FIFRA, with an emphasis on controlling diseases transmitted by mosquitoes and other vectors.

Dr. Hazeltine's June 8th testimony states, " . . . It should be obvious that for good mosquito and other vector control programs to continue, professional public health decisionmakers need to have a wide array of choices available to them, so that they can select the best material or method for use when control becomes necessary. If pesticides are not registered by the Federal Environmental Protection Agency (EPA) they are not going to be available for use to protect the Public's Health. While we continually look at a wide range of control alternatives, we recognize the need for effective pesticides which are registered and available for our use."

We would also like to point to the comments of Dr. John Graham which were shared with the House Subcommittee on Department Operations and Nutrition on July 14, 1993. Dr. Graham is Professor of Policy and Decision Sciences at the Harvard School of Public Health and founding Director of the Harvard Center for Risk Analysis. Dr. Graham's July 14th testimony makes a very convincing case for the human health benefits associated with the use of many pesticides. He states, " . . . In some situations, the loss of a pesticide may cause direct harm to public health as a result of consumer exposure to the fungi that thrive without the pesticide. For example, although many fungicides have been shown to cause cancer in animals at high doses, some of the toxins produced by fungi, such as aflatoxin, are also known to cause cancer. One of the benefits of pesticides is the human health protection resulting from destruction of fungi."

Many CPDA companies manufacture, formulate and distribute insecticides and rodenticides that attack mosquitoes, flies, ticks, mites, fleas and other insects, rats and other rodents, and that promote public health. Many of these companies, therefore, emphasize nonagricultural pesticide production and public health issues. Be-

cause we share Dr. Hazeltine's concern about public health issues, we at CPDA believe that the public health pesticide provisions of H.R. 1867 should be adopted as an amendment of FIFRA.

In summary, the Dooley-Herger bill recognizes the unique benefits of low volume minor use pesticide products which are widely used in public health programs to combat a host of insects and pests which transmit harmful diseases to man. It is critical that a wide variety of product choices be made available in order to maintain good mosquito and other vector control programs. Without proper public health programs, vector borne diseases such as malaria and yellow fever might once again become epidemic in the United States. We believe that the provisions contained in the Administration bill if adopted in combination with the Dooley-Herger bill will help ensure that this never happens.

OTHER IMPORTANT PESTICIDE LEGISLATIVE ISSUES

Additionally, we would like to comment on five other pesticide issues: (1) "Me-too" certification; (2) preemption; (3) synchronization and coordination; (4) minor use; and, (5) minor use and data compensation.

"ME-TOO" CERTIFICATION

The 1988 FIFRA "Lite" amendments mandated that the Agency establish a "fast track" or expedited review of "me-too" registrations and simple amendments (label changes), but the Agency has never fully implemented this provision. We strongly support section 112 of the amended version of H.R. 1627. This provision incorporates many of the initiatives advocated by the Antimicrobial Industry Coalition, that creates a certification registration process for substantially similar or identical pesticides. This important reform will expedite pesticide registrations and dramatically reduce the amount of Agency resources needed to register these products.

PREEMPTION

We at CPDA would like to express our support for legislation which would preempt local jurisdictions from enacting their own rules governing the sale and use of pesticide products. We believe that such regulatory authority over pesticides should be limited to a partnership between Federal and State governments which have the appropriate mechanisms in place to promulgate uniform, sensible regulation based on sound science.

On June 21, 1991, the Supreme Court issued its decision in the case of *Wisconsin Public Intervenor* v. *Mortier*. In its opinion written by Justice White, the Supreme Court ruled that local jurisdictions are not preempted by FIFRA from enacting their own pesticide ordinances. In essence, the Court's decision threatens to undermine the existing Federal-State partnership of pesticide regulation by opening up the field of regulation of these products to more than 80,000 units of local government.

At its July 27, 1994 FIFRA markup of H.R. 1627, the House Subcommittee on Department Operations and Nutrition passed an amendment which prohibits local governments from imposing any requirements or regulations regarding pesticides. The legislation, however, does not prohibit a State from enacting laws or implementing regulations applicable to local governments regarding the sale or use of any registered pesticide. This provision is identical to an amendment offered by former Representatives Charles Hatcher (D–GA) and Ron Marlenee (R–MT) during the May 1992 markup of FIFRA conducted by the House Subcommittee on Department Operations, Research and Foreign Agriculture (DORFA). At that time, CPDA and other members of the Coalition for Sensible Pesticide Policy, a broad-based industry alliance, fought very hard for the inclusion of the Hatcher-Marlenee language in FIFRA.

We remain committed in our support of legislation which would revise FIFRA to prohibit the local regulation of pesticides and urge the subcommittee to adopt the language contained in the amended version of H.R. 1627.

COORDINATION AND SYNCHRONIZATION OF FEDERAL/ STATE DATA REQUIREMENTS

We at CPDA strongly support legislation that would facilitate an increase in coordination and synchronization between the various States and the U.S. Environmental Protection Agency. Legislation to achieve these goals was introduced on November 22, 1991 (H.R. 3882, the "Pesticide Data Coordination and Synchronization Act of 1991") by Congressmen Steve Gunderson (R–WI) and Pat Roberts (R–KS). An identical measure was adopted by the House Subcommittee on Department Operations and Nutrition in its July 27, 1994 markup of H.R. 1627.

In 1984, California passed S.B. 950 to require the filling of pesticide data gaps, for all products, including lawn care chemicals. To implement this law, the State adopted a definition of a "data gap," created a list of tests that need to be completed, and established a detailed timetable for filling these data gaps.

The State legislature, however, did not take into consideration the attempt of the Congress to create their own reregistration timetables when it amended FIFRA in 1988. FIFRA "Lite" was also designed to fill these same data gaps. This is a new and growing problem. Several States are now considering such legislation and Arizona has followed California's example.

The bill, according to Representative Gunderson, would have required EPA to "coordinate and synchronize" data requirements at the State and Federal levels so as to "avoid unnecessary repetition and redundancy."

Representative Gunderson stated that the legislation "calls for communication and consultation concerning requirements for generation and review of specific data between State and Federal regulatory agencies, and will foster but not require uniformity."

In his remarks, appearing in the November 22, 1991 *Congressional Record,* Representative Gunderson said that by "reducing the increased pricing associated with the cost of unnecessary and redundant testing," the measure would help farmers and consumers faced with the rising cost of pesticide products.

"To illustrate the need for this legislation," the Congressman stated, "it is important to note that States have been adopting laws to establish programs for filling health and safety data gaps on pesticides registered within its borders."

"In some cases," he continued, "by establishing a list of required studies, and by creating a timetable for filling these gaps, the States will disregard the efforts of EPA to establish reregistration timetables and data call-ins to fill some of these very same data gaps."

"In essence," Representative Gunderson stated, "in attempting to establish their own expedited reregistration programs to fill data gaps, the States may establish their own data requirements, and those requirements can be at odds with EPA's and cause hardship for both active ingredient manufacturers and formulators of pesticides. Additionally, standards of review of existing or newly generated data may differ."

"*Unnecessary repetitive and redundant testing not only consumes valuable time and resources,* " the Congressman stated, "*but also delays the closing of data gaps. Valuable time and resources which could be used to develop new data are wasted in refocusing on gaps that have already been or are in the process of being filled.*"

In his statement, Representative Gunderson also noted that many low-volume, low-profit specialty products, including antimicrobial products, may be discontinued because neither the registrant, the formulator, nor the State will pay for additional tests required on active ingredients.

"*Many nonagricultural, minor use products also could disappear,*" he said. "*Unrealistic timetables for implementing and generating these needed studies could cause some of these products to be dropped from the market.*"

Concluding his remarks, Representative Gunderson stated that, "*With adoption of this provision, pesticide manufacturers can make well-reasoned decisions as to the generation of additional data. The entire process of filling data gaps will be greatly enhanced through the exchange of information between State and Federal toxicologists and other regulatory officials.*"

Coordination and synchronization legislation would help reduce the cost of pesticides, including lawn care chemicals, eliminate duplicative and unnecessary testing, expedite the closing of data gaps and make sure that pesticides for farmers and consumers, especially minor use products, will be available wherever needed.

We at CPDA are pleased that the provisions of Congressman Gunderson's legislation from the 102d Congress (H.R. 3882) has been incorporated into H.R. 1627, as amended by the House Subcommittee on Department Operations and Nutrition. We would urge this Senate subcommittee to adopt similar legislation in considering any amendments to FIFRA.

MINOR USE

CPDA supports the concept of the Minor Crop Pesticides Act of 1993, S. 985, introduced during the 103d Congress by Senator Daniel K. Inouye. Identical legislation, H.R. 967, was introduced by Representative E. (Kika) de la Garza, Chairman of the House Committee on Agriculture. The provisions of H.R. 967 have been adopted as part of the package of amendments to FIFRA legislation, H.R. 1627, during a House Subcommittee on Department Operations and Nutrition markup.

The retention of minor use pesticides used on low volume commodities should remain a key focus of Congress in the reauthorization of FIFRA. Minor crops grown in the United States constitute an industry with estimated sales of $35 billion at the farmgate. These include hundreds of different crops ranging from daily foods (fruits, vegetables, and nuts) to a variety of specialty items (flowers, hops, herbs, trees, shrubs, and turf).

As you know, under the 1988 amendments to FIFRA, the U.S. Environmental Protection Agency was charged with reviewing some 600 agricultural chemical active ingredients as part of its 9-year accelerated reregistration program targeted for completion in 1997.

Since its inception, we have witnessed a dramatic reduction in the number of minor use pesticide registrations. To date, 34 percent of the products originally registered have been dropped. The majority of these product registrations have been held by small companies. The financial burden of maintenance and reregistration fees in combination with the enormous costs of generating the necessary data to support the continued registrations of these chemicals have contributed to their decline. Today, a number of crucial products remain at risk of disappearing from the marketplace.

EPA's accelerated reregistration program has subjected registrants to a number of data submission requirements in defending pesticide registrations for use on minor crops. The costs associated with fulfilling these requirements is formidable when one considers that for each active ingredient, there may be a number of different product formulations used on a wide variety of crops.

The members of CPDA see S. 985 as a step in the right direction to ensure cost-effective chemicals remain available for use on low volume commodities. S. 985 supplies the flexibility to EPA in addressing minor use registrations. Time extensions, waivers, use of surrogate data, and the creation of a fast track process for these registrations provides the mechanisms needed to support the continued uses of these valuable chemicals. At the same time, the bill conditions these allowances on the certainty that there will be no unreasonable adverse effects on man or the environment.

Moreover, the measure adopts a very broad definition of minor use, encompassing uses of a pesticide on animals, commercial agricultural crops and public health pesticides. A determination of minor use activity is based on economic incentives, rather than on specific acreage requirements, a threshold found in previous minor use bills. As such, current EPA policy is ratified.

Furthermore, we support the creation of minor use programs in both EPA and USDA. Programs of these sort will help in coordinating policies, consulting with growers and tracking and expediting minor use registrations.

MINOR USE AND DATA COMPENSATION ISSUES

We believe that the mechanisms found in S. 985, such as extensions, certain waivers and use of surrogate data, in conjunction with the present data compensation provisions found in FIFRA, provide ample incentive for pesticide registrants to support these chemicals through the reregistration process and in developing new active ingredients.

While we support the major provisions of S. 985 and its counterpart in the House, H.R. 967, we believe the extension of time periods for exclusive use of data will not assist minor use protection, and, in fact, will actually exacerbate the problem.

The pesticide industry is similar in many ways to the pharmaceutical industry. Under FFDCA, there are limited provisions which grant patent term extension to cover, in part, some of the time lost in the FDA registration process, but it also includes provisions for generic drug registration, the elimination of data compensation provisions, and permits the testing of potential products 2 years prior to the expiration of the patent. These arrangements create a balanced package for both basic manufacturers and generic drug producers.

Currently, under FIFRA we find that in addition to the initial patent, the data used by a generic producer are compensated not at cost but at fully loaded value with market considerations such as early market entry. If Congress selected to extend the period of exclusivity, the result would be an unfair and inequitable solution that would only drive up the cost to farmers, ranchers, consumers and pesticide end-users. Moreover, it would destroy competition in the marketplace and would disproportionately impact small businesses that formulate or distribute many regional or local products.

We believe that these exclusive use provisions should be rejected for the following reasons:

- It will artificially inflate the costs of nearly all pesticides and create a 10-year period where the registrant can maintain a high price for all consumers and pesticide uses. This provision will affect millions of farmers, as well as countless millions of consumers who treat their lawns, shrubs, trees, and gardens.
- This 10-year exclusive use period will broadly affect *most* food use pesticides, including most of the List A and B food use products currently being reregistered.
- It will create a monopoly for basic registrants that will deny formulators and distributors an opportunity to market their products for specific minor uses and prevent entry into the market.
- It will create an economic disincentive to market existing products. For example, dealers and distributors will probably want to carry a product with the largest number of uses, and would not carry a product with 5, 10 or 15 fewer minor uses. In essence, a formulated product with fewer uses would be at a competitive disadvantage in the market place.
- It would extend protection far beyond patent term and provide de facto patent term extension.
- This period of exclusive use would particularly impact old chemicals being reregistered, and could effectively deny formulators and distributors entry into the local and regional markets for minor use products.
- The provision covers *all data* which solely supports a minor use. It is not restricted to just residue data.
- This provision is unneeded and unnecessary because sufficient economic incentives for data production for minor uses already exists under the EPA PR Notice 94–1 which provides for protection of data and compensation for that data. Under section III of the Notice entitled "Data Compensation Rights of Persons Who Develop Data," EPA affirms that "data developers who develop generic or use-specific data in support of registration or reregistration of a product are entitled to the same data compensation rights as MP registrants that develop such data. They may request that they be identified on the Agency's Data Submitters List, as wanting data compensation from registrants who use their data in support of registration. The request to be added to the Data Submitters List should include the name of the active ingredient, data for which compensation is required, and their firm's name and address." Please see an attached copy of PR Notice 94–1 as an appendix[22] to this testimony.
- This provision has a disproportional economic impact on small businesses that produce, formulate and distribute local and regional products for specific minor uses.
- Most importantly, this provision reopens the controversial Congressional deliberations over data compensation, generic data registration, patent term extension, and roll-back of the *Bolar* v. *Roche* decision that occurred in the 1980's. It devises a program that one-sidedly benefits large basic producers, and creates significant economic disadvantages for small producers, formulators and distributors and denies them an ability to compete in the marketplace.

Conclusion

We at CPDA respectfully urge the Senate Subcommittee on Agricultural Research, Conservation, Forestry and General Legislation to conduct a markup of FIFRA as soon as possible. We strongly support S. 1478 for its treatment of Delaney and tolerance setting, as well as cancellation and suspension. We ask that this subcommittee develop Senate language which would incorporate the provisions of H.R. 1867, the Dooley-Herger bill on public health pesticides. Similarly, we at CPDA recommend that this subcommittee adopt provisions found in H.R. 1627, as amended by the House Subcommittee on Department Operations and Nutrition. Specifically, CPDA supports those House provisions which address: 1) restrictions on local governments from regulating the sale and use of pesticides; 2) the coordination and synchronization of data between Federal and State agencies; 3) certification of "me-too" registrations; and, 4) labeling reform within EPA. In addition, we support Senator Inouye's minor use bill (S. 985), except for the provisions on 10 years of exclusivity. We strongly support fixing the registration and reregistration process so that products can be handled in an efficient, effective and expedited manner. We also support portions of S. 2050 and S. 2084, the administration's legislation to amend FIFRA and FFDCA, respectively, especially the public health provisions. We ap-

[22] See page 122.

plaud this Senate subcommittee for its leadership on pesticide issues and look forward to working with its members during the 103d Congress. We respectfully urge this subcommittee to draw on the best of the FIFRA and food safety legislative proposals which have been introduced in both the House and Senate as it proceeds in crafting a fair and reasonable pesticide reform package.

[APPENDIX]

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, DISTRIBUTORS, AND REGISTRANTS OF PESTICIDE PRODUCTS

Effective immediately, EPA is withdrawing PR Notice 91–8, entitled "Revised Policy To Provide Applicants Other Than Basic Manufacturers An Opportunity To Submit Generic Data and Receive Data Compensation For It. That notice requested the use of a generic label statement on manufacturing use product (MPs) to effect this policy. Persons who have complied with PR Notice 91–8 may retain such statements or may delete them from product labeling, at their discretion.

BACKGROUND

In the mid-1980's, the Agency developed a policy for Manufacturing Use Product (MP) labeling that uses supported by the MP registrant should appear on the label and that reformulation for other uses should be prohibited. During pesticide reregistration many MP registrants have elected not to develop data in support of some label uses of their products, especially the minor uses. In accordance with Agency policy, these uses must be removed from MP product labeling.

Certain grower groups and end-use formulators have decided to fill the void themselves by submitting generic data to support the registration or reregistration of those minor uses. However, the Agency's policy for MP labeling could have the unintended consequence of denying these user groups and formulators compensation from other formulators for this data as provided under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(c)(1)(F). Because the Agency's MP labeling policy prohibits an unsupported use from appearing on an MP label, these user groups and formulators must provide the data they intend to generate to an MP registrant in order to ensure that an MP can be reformulated lawfully for the minor uses that the data support. Once the MP is supported for such uses, however, other formulators using the MP may claim the formulator's exemption for those uses, thereby denying compensation to the user groups or formulators that developed the data. Therefore, several end-use registrants and user groups requested that the Agency establish a mechanism to ensure that the data compensation rights of grower groups and formulators generating minor use data are retained.

PR Notice 91–8 was the Agency's attempt to ensure compensation for data developed by grower groups or formulators by requesting MP registrants to include an additional generic labeling statement that permits reformulation of their products for uses other than those specifically listed on the MP label and supported by the MP registrant, provided the formulator supports such uses. This statement preserves the data compensation rights of grower groups or end-use formulators because the labeling statement would effectively prevent other formulators that did not develop data from claiming the formulator's exemption for specific uses supported by user groups or end-use formulators.

These same end-use registrants and user groups have now advised the Agency that MP registrants should not be required to adopt the generic labeling statement set forth in PR Notice 91–8. These groups have joined with the representatives of MP registrants in advising the Agency that MP registrants should be able to control the uses made of their products by controlling the MP label. They indicated that the user groups and end-use formulators must work in cooperation with the MP registrants before developing the necessary data to sustain a use which the MP registrant no longer intends to support. These groups, have, however, asked that the Agency affirm that the formulators, coalitions, manufacturers and grower groups that develop basic data are entitled to data compensation should another person rely on such data to obtain a registration.

AGENCY ACTION

Because representatives of grower groups and end-use formulators who requested PR Notice 91–8 believe that the Agency should not require MP registrants to adopt the label statements set forth in the Notice, the Agency sees no reason to continue the policy. Accordingly, the Agency withdraws PR Notice 91–8 and will not require MP registrants to incorporate the generic labeling statement set forth in PR Notice 91–8.

DATA COMPENSATION RIGHTS OF PERSONS WHO DEVELOP DATA

Although EPA is withdrawing PR Notice 91–8, it is not abandoning the principles underlying the notice. EPA affirms that data developers who develop generic or use-specific data in support of registration or reregistration of a product are entitled to the same data compensation rights as MP registrantsthat develop such data. They may request that they be identified on the Agency's Data Submitters List, as wanting data compensation from registrants who use their data in support of registration. The request to be added to the Data Submitters List should include the name of the active ingredient, data for which compensation is required, and their firm's name and address. Submit such requests to Ms. Sherada Hobgood at the address under VI below.

REGISTRANT ACTION

MP registrants who have complied with PR Notice 91–8 may continue to use the label statement set forth in the notice[23], or may delete it at their discretion. No notification is required solely for this purpose.

Any MP registrants wishing to do so may add one of the following statements to an MP label under "Directions for Use" to permit the reformulation of their product for a specific use or all additional uses supported by a formulator or user group. Furthermore, provided no other labeling changes are made, no notification to the Agency is required.

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s)."

(b) "This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such uses."

Note: This notice does not alter the Agency's basic labeling policy that MP registrants include a specific list on the label of those uses for which the MP may be reformulated.

Effective Date: Effective immediately PR Notice 91–8 is withdrawn.

Additional Information: For further information, please contact—Rosalind L. Gross, Registration Support Branch, Registration Division (7505–W), EPA, 401 M Street, SW, Washington, DC. 20460, (703) 308–8354.

POSITION STATEMENTS

The National Association of State Departments of Agriculture

The National Association of State Departments of Agriculture (NASDA) is pleased to submit testimony for the record on the matter of pesticide regulation reform. NASDA is the nonprofit association of public officials representing the Commissioners, Secretaries and Directors of Agriculture in the 50 States and the territories of American Samoa, Guam, Puerto Rico, and the Virgin Islands. As the Chief State Agriculture Officials, NASDA's members are keenly aware of the importance of balancing agricultural production and natural resource conservation on their State's and the Nation's economy.

In most cases, under a cooperative agreement with the Environmental Protection Agency (EPA), the State Departments of Agriculture serve as the Lead State Pesticide Regulatory Agency in each State. Therefore, NASDA brings a unique perspective on pesticide regulations and the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). NASDA members represent the frontline pesticide regulators who must balance human health and environmental protection

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[23] "Only for formulation into an _____, [fill blank with Insecticide, Herbicide, or the applicable term(s) which describes the type of pesticidal use(s)]. For (1) the following use(s): _____ (fill blank(s) with only those uses that are being supported by the MP registrant or applicant.) Conclude this statement by adding. (2) Uses for which U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and (3) Uses for experimental purposes that are in compliance with U.S. EPA requirements."

with farmers' needs, and face the State and local anxiety over pesticide use and regulation.

BACKGROUND

Under FIFRA, EPA is responsible for registering pesticides using risk-benefit analysis to ensure that pesticide use will not result in unreasonable adverse effects on health or the environment. EPA registers a pesticide only if it determines that it will not cause any "unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide. " Basically, registrations are licenses for specific pesticide uses that state the terms, conditions and cautions of these uses.

To register a pesticide, EPA requires the manufacturer to provide health and environmental effects data, product labeling information, a confidential statement of the chemical formula of the pesticide, and child-resistant packaging (if applicable) to EPA's Office of Pesticide Programs, Registration Division. It may take the applicant a few months to several years to gather the necessary data because of the time involved in completing the research required to obtain a registration. The Registrations Division decides to approve or deny the registration after reviewing a complete application. This process can take an average of 2 years if all the necessary data have been provided, but much longer if data is incomplete and additional data is needed.

Separate legislation guides the setting of tolerances for residues of pesticides registered under FIFRA. The Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish tolerances—the maximum limits of pesticide residues allowed in or on raw agricultural commodities, processed foods, or animal feeds. Establishing a tolerance is a prerequisite to granting registration for food-use pesticides used in the United States.

In order to establish a tolerance, EPA must determine whether tolerance levels proposed by pesticide registrants will present a health risk to the consumer. Registrants are required to submit toxicology and residue data in their tolerance petitions (applications) to assess possible health and environmental risks, to identify the nature and amount of residue that could occur with proper pesticide use, and to present analytical methods that the Food and Drug Administration (FDA) can use to test the food for residues of the pesticides. EPA scientists (reviewers) use this data to assess the possible health risks of a pesticide's use on food and to determine whether proposed tolerance levels would protect the public health. FDA enforces the EPA tolerances for both domestic and imported produce.

CONGRESSIONAL DEBATE

American consumers can be confident that the United States food supply is safe from unreasonable risks presented by pesticide residues. The food products available to U.S. consumers are safe, abundant and economical. NASDA does believe, however, that improvements in our pesticide laws are needed primarily due to advances in scientific technological capabilities.

As the national association of the State lead pesticide regulatory agencies and officials, NASDA believes that S. 1478, the Food Quality Protection Act of 1993, will improve Federal regulation of pesticide use and establish national uniform tolerances for residues in food based upon a "negligible risk" standard, as recommended by the National Academy of Sciences (NAS). Adoption of this legislation will allow the United States to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA strongly supports passage of S. 1478 and encourages the Senate Agriculture, Nutrition and Forestry Committee to move quickly to favorably report the bill. S. 1478 is the most balanced and responsible piece of legislation pending before Congress, and should be the vehicle used by this Committee in reauthorizing FIFRA.

The current debate over pesticide regulation reform boils down to a simple conflict between sound science and emotionalism. Responsible scientists from government, academia, and the industry have shown in no uncertain terms that pesticides can be safely used to provide strong benefits to consumers in the form of a safe, abundant and affordable food supply. Those who worry that any use of pesticides is somehow unsafe—despite overwhelming evidence to the contrary—have been overcome by the sensationalized emotional falsehoods perpetuated by "so-called" experts whose existence depends upon creating fear among the American consumer. These folks believe that pesticides should be eliminated across the board.

In April, the Clinton administration proposed legislation reforming the way pesticides are regulated. S. 2050 (amendments to FIFRA) and S. 2084 (amendments to the FFDCA) would implement the administration's plan which unfortunately echoes

the beliefs of the "chemophobes" lobby. In those bills, emotion and scare tactics seem to prevail over sound science.

The focus of S. 2050 and S. 2084 is on eliminating the use of pesticides rather than on ensuring their safe use. Some of the proposals put forward by the administration may sound sensible, but most are unworkably rigid and would provide real problems for farmers and food producers. Most importantly, they are ultimately contrary to the best interests of consumers. If the administration's proposals are enacted, it is likely that we will see food scares over hypothetical risks that don't exist in the real world. Adoption of the administration's plan will see the loss of important, safe crop protection tools to farmers, coupled with an increase in food prices and a decrease in availability and quality of food.

The most disturbing situation that has been created by the administration's bills is the likely scenario that no pesticide regulation reform will be passed in this Congress. The 103d Congress needs to pass pesticide legislation. The industry faces problems created by the conflicting and confusing regulations of FIFRA and the FFDCA, and consumers need to have their confidence in the food supply reassured. Both of these objectives can only be achieved by passage of a bill which improves the situation; one which allows producers to enhance the quality and availability of a safe and nutritious food supply. S. 1478 accomplishes that; S. 2050 and S. 2084 do not.

RIGID NEGLIGIBLE RISK STANDARD

NASDA is specifically concerned that a negligible risk standard not be defined by reference to a specific acceptable numerical risk level, either in statutory language or legislative history. It is essential that EPA maintain flexibility to take account of evolving scientific standards and to consider all relevant safety and exposure information. S. 1478 allows EPA to employ its expert judgment unhindered by a numerical straightjacket.

While S. 331 (the Pesticide Food Safety Act of 1993 introduced by Senator Edward Kennedy) eliminates the Delaney clause, it replaces Delaney with a so-called bright-line standard which would prohibit EPA from setting a tolerance under any circumstances for a pesticide posing more than a one in one million lifetime cancer risk based on conservative risk assessment methods. This inflexible standard would unreasonably restrict EPA's expert judgment and would preclude consideration of advances in toxicological science and risk assessment.

The administration's proposal does eliminate the Delaney clause and replaces it with a narrative negligible risk standard. It, however, creates a dual tolerance system—one tolerance at the farm gate, and the potential for a second tolerance at the supermarket. This new, undefined two-tolerance system does not meet the objective of *one* safety standard for all foods, and, in fact, will cause increased confusion for consumers as well as regulatory problems.

LIMITATION OF BENEFITS

S. 1478 would make clear that EPA may establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that there are countervailing benefits. EPA would be directed to take into account health, nutritional and consumer benefits, including the impact of the loss of a pesticide on the availability of an adequate, wholesome and economical food supply. EPA would be precluded from considering any impact on pesticide manufacturers or distributors. NASDA believes this language must be included in any pesticide reform legislation.

The administration proposal would greatly limit the types of benefits that could be considered in pesticide tolerance decisions, would prohibit the continuation of a tolerance based on exceptional benefits beyond 5 years, and would prohibit any consideration of benefits in tolerance decisions after 10 years. The proposal would prohibit EPA from taking into account the value of a pesticide in maintaining an adequate, wholesome and economical food supply unless it could be proven that loss of the pesticide would cause a "significant disruption in the food supply" and would have a profound effect on consumer prices. This limited benefits consideration will expire after the 10-year period. NASDA strongly opposes this narrow benefits standard which would be virtually impossible to satisfy. Prohibition of consideration of benefits for pesticide tolerances would deprive growers of pesticides for which there are no alternatives, would undermine the nutritional welfare of consumers and would not achieve a meaningful risk reduction.

LIMITATION ON USE OF REALISTIC EXPOSURE DATA

NASDA supports the administration's stated goal of using the best available exposure information, including actual pesticide use and residue data, in setting pes-

ticide tolerances. However, the administration's proposal would prohibit the use of actual exposure information (including pesticide use and residue data) and would require use of worse case assumptions unless the registrant could satisfy a heavy burden of proof. Tolerances based on actual exposure data would be subject to discretionary periodic reconsideration and a possible requirement for separate tolerances for raw commodities and processed food. NASDA believes these evidentiary and procedural hurdles would compel the use of exaggerated exposure assumptions and inflated risk estimates in virtually all tolerance determinations.

ACCELERATED TOLERANCE RENEWAL

The administration proposal would generally provide for renewal of pesticide tolerances over a 7-year period in conjunction with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) reregistration. Special expedited renewal, over a 4-year period, would be required for pesticides identified by EPA as having a high risk potential. NASDA believes this accelerated review provision is impractical, could conflict with the FIFRA reregistration process and would give EPA excessive discretion to eliminate valuable food use pesticides without the procedural protections of the FIFRA cancellation process.

"PHASE-OUT/PHASE-DOWN OF PESTICIDE REGISTRATIONS

NASDA believes it is unnecessary to give EPA entirely new authority to phase-out/phase-down the use of a pesticide where "credible scientific evidence shows a pesticide is reasonably likely to pose a significant risk to humans or the environment." NASDA believes such authority would encourage EPA to circumvent the FIFRA cancellation process. It would empower EPA to limit or prohibit the use of a pesticide without the external scientific review and procedural protections in the cancellation process, without any consideration of the pesticide's benefits and on the basis of toxicological evidence that is too weak, incomplete or inconsistent to support a complete risk analysis. Phase-out orders would generate damaging adverse publicity, disrupt sales of food products and cause irreparable harm to food producers and consumers. With the modification proposed to cancellation and suspension by S. 1478 and the administration proposal, this new vaguely defined concept is completely unnecessary.

CANCELLATION AND SUSPENSION

NASDA believes that statutory changes are necessary to permit EPA to remove hazardous pesticides from the market with reasonable speed. Both the administration proposal and S. 1478 would eliminate the adjudicatory hearing process for cancellation procedures, and suspension actions would be decoupled from cancellation procedures. Accordingly, we strongly support these provisions to streamline and speed-up the suspension and cancellation procedures. NASDA believes a provision should be included which would provide an expedited process to retrieve chemicals from the end-user (farmer) which have been canceled and suspended.

REREGISTRATION PROCESS

The administration proposal calls for a reregistration of all products every 12 years. NASDA supports a reregistration program for all pesticides in order to maintain current and accurate data on products. EPA should be required to provide adequate lead time for the submission of any new data requirements. Additionally, the reregistration process should be made less costly and time consuming, allowing the Agency to achieve reregistration is a more efficient manner.

TOLERANCE UNIFORMITY & FEDERAL PREEMPTION

A tolerance uniformity provision is indispensable to preserve EPA's leadership in pesticide regulation and to avoid the consumer confusion and unreasonable burdens on interstate commerce caused by special State tolerance requirements. NASDA strongly supports the uniformity provisions of S. 1478.

Pesticide use regulations are best enacted and coordinated at the State level or higher. In this way, conflicting and overlapping regulations may be avoided, and greater access to scientific expertise and input is available. With greater citizen input at the State level, action taken will benefit all residents of the State rather than one isolated town or village. NASDA supports sensible, uniform Federal/State regulation of pesticides through passage of preemptive legislation, while allowing local input into the Federal/State regulatory process.

FDA ENFORCEMENT AUTHORITY

FDA already possesses ample enforcement power with respect to food violations, including seizure, injunction and broad criminal penalty authority. NASDA does not believe there is a demonstrated need for FDA to have the additional enforcement authority called for in the administration's proposal, such as recall, embargo and civil penalty authority for pesticide tolerance violations. This would give FDA excessive discretionary authority without protecting the due process rights of regulated parties. There is also no reason for FDA to have different enforcement authority for pesticide tolerance violations than for other food infractions.

PRIVATE RIGHT OF ACTION

NASDA strongly opposes the concept of citizen suits against EPA, State regulatory agencies and commercial applicators for any violation of FIFRA as provided for in the administration's proposal. Such a provision is wholly unnecessary and only encourages frivolous lawsuits and disrupts agricultural production. There is no evidence that EPA is unable to adequately enforce FIFRA or that a private right of action provision would meaningfully enhance pesticide safety.

PESTICIDE RECORDKEEPING

NASDA strongly opposes expansion of the 1990 Farm bill recordkeeping requirements to cover all farmers who apply any general use pesticides as provided for in the administration's proposal. Claims that such a requirement is necessary because USDA does not have sufficient data only points to the failure of data collection, not the failure of farmers to keep records.

As regulators of pesticide application and pesticide recordkeeping, NASDA's members believe such a provision would be absolutely impossible to enforce since those who apply general use pesticides—categorized as such because of their nonthreatening environmental nature-do not have to, in any way, be identified.

REDUCED USE

The administration proposal calls for a joint EPA–USDA chaired effort to, within 1 year, develop commodity-specific pesticide use reduction goals. Under the proposal, the statute would clearly state a policy goal "favoring reduced use and direct Federal agencies to take a leadership role in promoting use reduction and IPM [Integrated Pest Management] in their programs." The plan calls for implementation of IPM practices on 75 percent of all production land.

While NASDA believes that IPM programs need to be encouraged, the administration uses the terms "IPM," "reduced use," and "sustainable" interchangeably. IPM programs do not necessarily mean reduced use, but more efficient and effective use of crop protection chemicals. Any legislative goals must clearly define IPM and recognize the difference in the three terms.

NASDA supports the administration proposal calling for the elimination of the prohibition on requiring IPM training as part of the certification and training programs. NASDA also looks favorably on the concept of "prescription use" of certain pesticides in an IPM program only as an alternative to complete loss of the pesticide. Such authority allows the retention of pesticides which may otherwise be canceled, and should not become yet another mechanism to reduce production tool options. This administration request for "prescription use" further points out the need to allow benefits consideration when registering pesticides.

MINOR USE

NASDA strongly supports the minor use provisions contained in S. 985 and believes this legislation will go a long way toward correcting the problem created inadvertently by the 1988 amendments to FIFRA which have led to the loss of necessary minor use crop protection chemicals. While the minor use issue is an economic one and not a food safety issue, it is extremely important to resolve the issue. The administration proposal includes aspects of the minor use provisions contained in S. 985, but it is incomplete and lacks the specificity of S. 985. NASDA, therefore, recommends that the language of S. 985 be used in place of the administration's proposal. If a comprehensive bill cannot be worked out, NASDA suggests that S. 985 be passed as a stand-alone bill.

STREAMLINE LABEL CHANGES

NASDA believes the administration's proposal calling for an annual uniform labeling effective date allowing registrants to make label changes in a predictable, or-

derly fashion, would dramatically speed and simplify the process for making changes.

EXPORT OF PESTICIDES

The administration's proposal would ban the export of any pesticide that has been canceled in the United States based on health concerns or environmental reasons. NASDA supports a ban on exports for any pesticide canceled for health based reasons. NASDA believes this broader prohibition is unnecessary and opposes such a provision. The United States does not allow food products to be shipped into the United States unless there is a food tolerance, eliminating concerns about nonregistered products used in a foreign country and then imported to the United States. It is further inappropriate for a developed country, such as the United States to mandate its environmental agenda on developing countries whose major production goal may well be feeding its people.

THE NATIONAL COTTON COUNCIL OF AMERICA

The National Cotton Council appreciates the opportunity to present testimony to the Subcommittee on Agricultural Research, Conservation, Forestry and General Legislation regarding food safety issues and the administration's pesticide reform proposal.

The National Cotton Council is the central organization of the U.S. cotton industry. Membership includes producers, ginners, warehousers, merchants, oilseed crushers, cooperatives and textile manufacturers. Most of the industry concentrates in 17 cotton-producing States, reaching from Virginia to California. The downstream manufacture of cotton apparel and home furnishings and of cottonseed products, however, occurs throughout the Nation.

While cotton's annual farm gate value is a significant $5 billion, perhaps a more meaningful measure of the industry's value to the U.S. economy is its retail impact. The business revenue generated annually by cotton and its products exceeds $50 billion. Cotton stands above all other field crops in its creation of jobs and its contribution to the U.S. economy. The industry, its suppliers and the manufacturers of cotton and cottonseed products, account for 1 of every 13 jobs in the workforce.

The Council commends the administration for its hard work in developing pesticide reform legislation. The issue of food safety is complex and any attempt to change the present law will have far reaching consequences, especially in the area of risk benefit analysis. We have concerns about many of the provisions in the administration's bill and therefore cannot support it.

Our concerns about the administration's proposal include provisions which address: (1) The way pesticide safety standards are set—the Administrations's bill would impose an unrealistic conservative and all too rigid safety standard for pesticide tolerances. (2) The methods of assessing products already on the market—phase-out orders could empower EPA to limit or prohibit the use of pesticides without the external scientific review and procedural protection guaranteed under the cancellation process, and without any consideration for the pesticide's benefits. (3) Requirements for multiple tolerances—EPA would be authorized to set unnecessary multiple tolerances for a pesticide on a single food at different points in the distribution chain. (4) Expanded recordkeeping requirements—EPA would also have the authority to add more requirements to the present recordkeeping program and inspection procedures on pesticide user premises. (5) Enforcement policies—FDA is granted broad new enforcement power, including recall, embargo and civil penalty authority with respect to pesticide tolerance violation. And most importantly, (6) provisions relating to consideration of risks and benefits—"health benefits" would not include benefits from an adequate, wholesome or economical food supply.

Addressing risk and preserving benefits are essential components to any credible food safety law or regulation. The administration's proposal limits and eventually eliminates benefit considerations for tolerances and a rigid negligible risk standard for tolerances is established. This is of great concern to our organization.

The American consumer has access to the most abundant, nutritious and affordable supply of food and fiber in the world. The benefits derived from this food and fiber supply are essential to a healthy diet and the health of our economy. The contribution that farmers make to feeding and clothing our Nation as well as others in the world is significant. Most farmers use only inputs that are necessary to produce the crop, and new techniques have been introduced in all areas of crop production.

However, American consumers seem to be increasingly concerned about the safety of their food. Part of this concern may be explained by distance and dependence. As the farm population shrinks to about 2 percent and more and more of our citizens depend on others to grow and prepare their food, their understanding of farming practices and food production has decreased. This may result in a decrease of confidence in the safety of our food supply.

To some extent, this has been exploited and scare tactics have been employed whereby the public becomes confused and misinformed about important issues. For example, we are all familiar with the controversies associated with Alar on apples and the use of irradiation in food processing.

Agricultural production has undergone a radical transformation in the last 30 years, especially in the area of cotton production. For example, field preparation practices reflect the varied environments and production Systems encountered across the U.S. growing regions. Conservation tillage Systems are gaining in popularity in areas subject to soil erosion. Conservation tillage, which includes, minimum till, no till and other forms of maintaining residue on the soil surface, has enabled farmers to increase their production options in response to their specific challenges. These systems became feasible with the advent of specialized equipment and new herbicide chemistry that reduce or eliminate the need for extensive tillage.

Integrated Pest Management is practiced throughout the U.S. cotton belt. This approach optimizes the total pest management system by utilizing all available tools, including rotation, crop residue destruction, maximum crop competitiveness, earliness, pest scouting, action thresholds and high selective crop protection chemistry. New chemicals coupled with good IPM schemes are helping to reduce grower reliance on prophylactic, protective treatments in favor of responsive, as-needed treatments. Insect management continues to evolve as selective chemistry and Bt transgenic cottons reach commercialization.

Also, cotton fertilization practices have undergone dramatic changes in recent years. Supplying nutrients as the crop demands has replaced traditional methods, as soil and tissue testing have become widespread.

The Council supports S. 1478 a bill introduced by Senators Pryor and Lugar. We believe that the provisions in this bill give regulators the flexibility that they need to apply the latest scientific data and technology to pesticide standards. The Delaney paradox is addressed by establishing a single, flexible negligible risk standard for pesticides residues in raw commodities and processed food. National uniformity is provided for setting tolerances and the pesticide cancellation and registration process is streamlined. However, what is most important is that benefits are considered when weighing risks.

Provisions in this bill allow EPA to consider benefits in setting tolerances for pesticide residues on raw commodities and would extend that power to tolerances for pesticide residues on processed food. EPA would be directed to take into account health, nutritional and consumer benefits, including the impact of loss of a pesticide on the availability of an adequate, wholesome and economical domestic food supply.

The importance of these benefits should not be underestimated. All American consumers should be able to purchase food that is safe, nourishing, and affordable. Furthermore, a realistic assessment of risks and benefits should be part of all food policy.

We believe that the provisions in S. 1478 support these goals and we urge Congress to act on this legislation and its companion bill, H.R. 1627, introduced by Representatives Lehman, Bliley, and Rowland in the House of Representatives.

SENATOR HELMS' QUESTIONS FOR DR. KESSLER WITH RESPONSES THERETO

REGULATION OF BRANDS

Reference. Dr. Kessler, on February 25, 1994, you said that if the Food and Drug Administration (FDA) asserts jurisdiction over tobacco as a "drug," the FDA might ban brands that smokers are currently smoking; but because you recognize the upheaval that would cause, you would also consider a so-called weaning period.

I doubt the American people would stand for such a heavy-handed action on the part of the Federal Government. Certainly this Senator will not.

That said, this preposterous statement raises some questions:

Question 1. Who will enforce this "weaning" period—do you envision some sort of Federal police force?

Question 2. Would the Federal Government inform the many Americans who smoke how long before they must quit smoking specific brands, allowing for no variation among individuals?

Question 3. If your claim that many smokers are addicted to tobacco is correct, would the FDA have a prolonged weaning period for these addicted smokers, and if so, for how long will the "weaning" period be extended?

Question 4. After the weaning period during which smokers are to abandon the brands you select is concluded, how will the Federal Government enforce compliance, and do you envision searches of smokers homes to be one of the methods of enforcing compliance?

Question 5. Is it fair to assume that those who continue to smoke brands which you decide to ban would be engaging in illegal activity, and if so, what penalty do you envision?

Question 6. Given the physical harm that other substances cause—including alcohol—has the FDA ever considered conducting an investigation similar to the one conducted on tobacco for alcohol, and if not, why not?

Response. The FDA is actively considering whether tobacco products containing nicotine, an addictive substance, are subject to the requirements of the Federal Food, Drug, and Cosmetic Act. This undertaking is of paramount public importance in part because more than 40 million Americans use tobacco products and tobacco use is considered to be the single leading cause of preventable death in the United States. It results in more than 400,000 deaths, and considerably more severe disability each year.

The Agency is engaged in the investigation of nicotine-containing tobacco products, and is evaluating all responsible actions that might be effective in reducing new addiction to nicotine, which today almost always occurs during childhood, while at the same time humanely addressing the needs of the 40–50 million people currently using tobacco products. As you may know, research has revealed that the overwhelming majority of these individuals desire to quit but cannot because of nicotine addiction.

At present, the Agency has made no decision with regard to asserting its jurisdiction nor what courses of action might be appropriate if jurisdiction is asserted. Your first set of questions specifically focuses on the idea of gradually reducing nicotine in cigarettes. That is certainly an interesting idea. We are enclosing a recent article that appeared in the *New England Journal of Medicine* on the subject that you may find useful. Because FDA has not determined that this is the course of action that we will pursue, it is not possible for us to provide you details of how such a policy might be implemented.

Regardless of the course of action FDA pursues, the Agency would not take enforcement action against consumers as you suggest in questions 1–5. In regulating drugs, the Agency places responsibility for accurate labeling and responsible marketing on drug manufacturers, not on consumers.

On August 1–3, FDA's Drug Abuse Advisory Committee met to consider questions relating to nicotine and addiction and reaffirmed the conclusions of the 1988 Surgeon General's Report that cigarettes and other forms of tobacco are addicting, and that nicotine is the drug in tobacco that causes addiction. They also agreed that there is probably a daily dose of nicotine from cigarettes and other tobacco products below which addiction is very unlikely, but could not identify what that dose is. Their deliberations might also be of interest to you.

In regard to question 6, unlike tobacco, all alcohol-containing products intended for human consumption are already subject to FDA safety regulation.

TOBACCO PROCESSING

Reference. On March 25, 1994, before a House subcommittee, you appeared surprised that a cigarette isn't simply a tobacco leaf rolled into paper. What is well-known to anyone even remotely familiar with the business is that cigarette manufacturers use a variety of processes in producing their products, very much like other commercial products.

Question 7. Would you have preferred that the companies had *not* used such processes, and instead, had offered the consumer their version of a good, old "roll your own" cigarette?

Question 8. Are you aware that the manufacturing processes you refer to as "manipulation" have-according to the Federal Trade Commission—resulted in a sharp decline in tar and nicotine levels over the last 40 years?

Question 9. Are you inferring that smokers are better served by smoking "roll your own" cigarettes or any other methodology than the brands on the market

today, including the low-yield ones, and if so, wouldn't this be even more of a public health risk?

Response. Our inquiry is focused on the evidence that cigarette companies may be using a variety of manufacturing processes to manipulate and control nicotine levels so that many people buy cigarettes to satisfy their nicotine addiction. This issue is critical to the central question of whether nicotine-containing cigarettes and other tobacco products should be subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

In regard to the level of nicotine in cigarettes today compared to 40 years ago, the critical issue is not whether it has gone up or down, but rather whether the level set is sufficient to satisfy an addiction on the part of smokers. Virtually all of the cigarettes sold in the United States today contain a level of nicotine well in excess of what is needed to sustain addiction. Smokers interested in quitting smoking or seeking to reduce the harm caused by cigarettes will be better served only when they have the freedom to choose whether or not to smoke. As most smokers themselves testify, when you get hooked as a child, as virtually all smokers do, not much choice is left.

MANIPULATION IN OTHER INDUSTRIES

Reference. Dr. Kessler, you've created a "buzz-word" term in your fight against tobacco called "manipulation." Except, you seem to apply it only to a means of producing products that you don't particularly like—specifically tobacco products.

Question 10. What are the short term and long term effects of alcohol consumption?

Response. The health effects, including risks and even possible benefits, of regular, low-dose exposure to alcohol is an issue of ongoing discussion in the medical community.

Heavy and chronic drinking, however, can harm virtually every organ and system in the body. As the primary site for alcohol metabolism, however, the liver is particularly vulnerable to the harmful effects of excessive alcohol consumption. The injurious effects of alcohol on the liver can lead to the development of fatty liver, alcoholic hepatitis and fibrosis, and cirrhosis.

Excessive alcohol use can also have harmful effects on the cardiovascular system. Heavy drinking may be associated with hypertension, weakened heart muscle, and increased risk of hemorrhagic stroke and arrhythmias.

Chronic alcohol abuse appears to adversely affect the immune system. Research suggests that alcohol depresses immune function, thus placing heavy drinkers at increased risk for infectious diseases.

Numerous studies have found that alcohol may have deleterious effects on the endocrine system and reproductive function. In men, alcohol can suppress testosterone levels, among other effects. In women, chronic alcohol use is associated with menstrual cycle disturbances.

Acute and chronic drinking may have multiple neurologic effects. Neurological consequences of alcohol exposure include acute alcohol intoxication, alcohol withdrawal, and nutritional diseases of the nervous system secondary to alcoholism.

For additional information you may consult with the National Institute on Alcohol Abuse and Alcoholism or refer to the Eighth Special Report to the U.S. Congress on Alcohol and Health from the Secretary of Health and Human Services or the 13th Edition of Public Health and Preventive Medicine, Chapter 43, Alcohol-related Health Problems.

Question 11. Inasmuch as manufacturers of some alcoholic beverages and products vary the alcoholic content of their products—alcohol-fortified wines being one example—are these manufacturers "manipulating" their product?

Response. Beverage alcohol is subject to intensive Federal, State, and local controls intended to reduce the risk alcohol poses to vulnerable individuals. There are many products and beverages, containing varying amounts of alcohol, in three major categories: wines, distilled spirits, and malt beverages. The alcohol content differs widely for products within each category depending on the various fermentation and distillation processes used, including, among other things, the substances being fermented (sugars, fruits, grains, or any of their parts or products) and storage conditions (*charred* vs. *uncharred* and *new* vs. *used oak containers for distilled spirits*). There are many combinations or formulas used in fermenting and distillation, and each produces a unique product of varying alcohol content and whose identity is defined in Title 27 of the Code of Federal Regulations (C.F.R.). The regulations do not identify a class or type of wine as "alcohol-fortified;" however, they do identify aperitif and blended wines which contain added brandy or alcohol. The acceptable ranges

of alcohol content for these products are stated in the C.F.R. The level of alcohol in beverage products is strictly regulated to protect the public.

Directive. Please list all alcoholic beverages and products, the contents of which are "manipulated" by the manufacturer.

Response. The products and beverages containing alcohol are too numerous to list. Alcohol is present in many drugs and beverages. With respect to beverages, within the major categories, there are nine classes of wines and 12 classes of distilled spirits. Within each class there are different types of beverages that have varying alcohol contents. There are hundreds of different alcoholic beverages, all currently subject to Federal oversight and safety regulation.

Question 12. What are the short term and long term effects of caffeine consumption?

Response. The most notable effects after intermediate doses of caffeine (100–250 mg) are increased alertness, energy, and ability to concentrate. Higher doses may induce anxiety, restlessness, insomnia, and tachycardia. Sleep disturbance has also been described.

Physical dependence on caffeine has been reported. The abstinence symptoms most frequently associated with caffeine withdrawal are headache, fatigue or lethargy, and anxiety. These can vary in intensity from mild to severe. Studies estimate that 5–10 percent of caffeine users suffer adverse effects or exhibit withdrawal symptoms.

Long-term effects of coffee or caffeine have been difficult to substantiate, and initial trials showing coffee's association with coronary disease and myocardial infarction, as well as other potentially negative outcomes, have been inconclusive.

Question 13. Inasmuch as caffeine is not a naturally occurring component of cola, are manufacturers of soft drinks containing caffeine "manipulating" their product?

Response. The FDA placed caffeine and hundreds of other substances on the "generally recognized as safe" (GRAS) list in 1961. Over the years, the Agency has reassessed the GRAS list and commissioned a committee to investigate these substances. Currently, caffeine is recognized as safe when used in cola-type beverages in accordance with good manufacturing practices and does not exceed .02 percent by weight (21 C.F.R. 182.1180). It is well established that a caffeinated beverage would be deemed adulterated if the quantity of caffeine added created a reasonable possibility that the beverage was "injurious." Products containing high levels of caffeine, or parenteral forms of caffeine, are regulated as drugs.

Directive. Please list all products containing caffeine, the contents of which are manipulated" by the manufacturer.

Response. Caffeine can be found in a variety of products including coffee, tea, cocoa, soft drinks, and chocolate. It is also an ingredient in a number of prescription drugs and hundreds of over-the-counter drug products, including analgesics, stimulants, diet preparations, and cold products. Drug products which contain caffeine are labeled in accordance with FDA monographs and/or regulations (21 C.F.R Parts 300 ff.). The amounts of caffeine contained in over-the-counter products are listed on the product label. Information on the amount of caffeine contained in prescription drugs can be obtained from the dispensing pharmacy, the package insert, or any number or pharmaceutical references, such as the Physician's Desk Reference or the American Drug Index. In all such products, the maximum level of caffeine has been regulated to protect the public.

INCOMPLETE PUBLIC STATEMENTS

Reference. During your testimony before a House subcommittee on June 21, 1994, you stated that you were not there to judge what's right or what's wrong or characterize any statements.

In your testimony, you stated: "A major American tobacco company spent more than a decade quietly developing a tobacco plant with exceptionally high nicotine levels, growing it in Central and South America, and ultimately using it in American cigarettes."

Question 14. Why did you omit from your testimony the fact that the brands containing this particular type of tobacco included essentially the same nicotine level as the products they replaced?

Also in your testimony before the House subcommittee, you stated, "Many people have wondered why the cigarette industry would add ammonia compounds to to-

bacco products. . . Our investigation has revealed another important use: to affect the delivery of nicotine to the smoker."

The tobacco companies have since then issued press releases saying that ammonia compounds in cigarettes do not alter the amount of nicotine the smoker inhales.

Who is right, you or the tobacco companies?

Response. Our June 21, 1994, testimony concerning Brown & Williamson's decade-long interest in the high-nicotine "Y–1" variety of tobacco emphasized that the company and its contractors possessed both the technical capability and the willingness to develop tobacco plants with higher than normal levels of nicotine. In this particular case, the specially bred Y–1 plant contained approximately twice the level of nicotine naturally found in similar commercially sold varieties of tobacco.

The patent for the Y–1 tobacco variety stated, in fact, that, "The nicotine content of the leaf of this variety is usually higher than 6 percent by weight . . . which is significantly higher than any normal variety of tobacco grown commercially. " Moreover, Brown & Williamson characterized its achievement in a patent filing by describing the Y–1 variety as providing a "pleasant taste and aroma when included in smoking tobacco products, yet it is possessed of the N. rustica high nicotine attribute. So far as we know, this has not been accomplished before . . ."

Previously, when we inquired whether plants were bred specifically for higher nicotine content, we were told that this was not feasible. Brown & Williamson officials told us that their firm did no plant breeding research or development, according to the sworn statements of four FDA officials present at a visit to the company's Macon, Georgia, facilities on May 3, 1994.

These facts buttress one of the central points first made in our March 25, 1994, testimony before Congress: That tobacco companies may be controlling smokers' choice by controlling the levels of nicotine in their products in a manner that creates and sustains an addiction in the vast majority of smokers. Previously, Brown & Williamson and other tobacco companies insisted that "nicotine follows tar" in cigarettes, meaning that tar and nicotine levels are not set independently. The significance of the development of the Y–1 plant was that it enabled Brown & Williamson to maintain the level of nicotine in cigarettes while reducing tar.

As we revealed in our June 21, 1994, testimony before Chairman Waxman's subcommittee, a major cigarette manufacturer's 1991 handbook states that adding certain ammonia compounds alters "the ratio of extractable nicotine to bound nicotine in the smoke . . . in favor of extractable nicotine. As we know, extractable nicotine contributes to impact in cigarette smoke and this is how ammonia can act as an impact booster." The handbook indicates that this ammonia technology enables more nicotine to be delivered to the smoker than if the ammonia technology is not employed.

In his testimony before Chairman Waxman's subcommittee on June 23, 1994, Brown & Williamson Chairman Thomas E. Sandefur, Jr., testified in response to a question from a subcommittee Member that "it is my understanding that ammonia does have the ability to provide for free nicotine . . . " In addition, Mr. Sandefur testified that "a number of tobacco manufacturers . . . use ammonia."

TAR AND NICOTINE MEASUREMENTS

Reference. The tar and nicotine yields found in cigarettes are based on methodology developed by the Federal Government, not the tobacco industry. In fact, the Federal Trade Commission measured the levels of tar and nicotine itself.

Yet, the FTC closed its laboratory doors because they couldn't justify the cost of these reports since their results almost always replicated that of the Tobacco Institute Testing Laboratory. The FTC does, however, oversee the levels that are reported by the industry and has the authority to verify them or bring an action against the industry for deceptive advertising practice.

Question 15. When you claim that smokers of low-yield brands of cigarettes do not receive lower levels of nicotine, are you implying that the FTC, as well as the tobacco industry, are deceiving smokers into thinking they are getting lower nicotine levels?

Response. Beginning in 1983, the FTC became aware of questions about the industry-developed methodology for measuring tar and nicotine yields in cigarettes, the so-called FTC numbers. As cigarette manufacturers themselves noted in the matter of Barclay cigarettes, there was reason to question how meaningful these numbers were. Experts within FTC and elsewhere concluded that these measurements did not reflect actual human intake, and thus had the potential to be misleading.

Recently, the FTC formally raised the issue of the actual utility of the method in a letter to National Cancer Institute (NCI) Director, Samuel Broder, M.D. The FTC

letter 9 article noted broad concern as to whether yield determinations by the FTC method mislead consumers as to relative risk of smoking cigarettes of varying yields, and requested that NCI convene a formal consensus conference to evaluate the utility of FTC's current method and make recommendations based on that evaluation.

It is FDA's understanding that NCI has decided to sponsor such a conference in the fall. We will briefly summarize the basis for the concerns of FDA, FTC, and others with the current FTC method.

In our testimony before the House subcommittee on Health and the Environment on March 25, 1994, we presented independent scientific data demonstrating that the automated smoking machine method of testing for cigarette tar and nicotine yields, currently employed by the Tobacco Institute Testing Laboratory and sanctioned by FTC, produces yields that do not correlate to yields in actual smokers. Specifically, the data show a lack of correlation between smoking machine nicotine yield and blood levels of nicotine in smokers. In our testimony, we discussed several confounding factors identified by researchers (smoker compensation, smoker blocking of ventilation holes, increased rate of cigarette paper burn, and extension of the cigarette overwrap) that contribute to the lack of correlation of smoking machine yields to nicotine blood levels. Smoker compensation primarily reflects the extent to which human smoking behavior differs from the FTC machine. However, placement of ventilation holes, cigarette paper burn rate, and overwrap length are confounding factors that are clearly within the control of cigarette manufacturers.

The statements in our testimony are supported by the following peer-reviewed journal articles.

— Pillsbury HO, Bright CC, O'Connor KJ, Irish FW. *Tar and nicotine in cigarette smoke*. J. Assoc. Offic. Analyt. Chem. 1969;52(3), 458–462.

— Benowitz NL, Hall SM, Herning RI, Jacob P, Jones RT, Osman AL. *Smokers of low yield cigarettes do not consume less nicotine*. NEJM 7/21183;309(3): 139–142.

— Herning RI, Jones RT, Bachman J, Mines AH. *Puff volume increases when low-nicotine cigarettes are smoked*. Brit. Med. J., 7/18/81;283: 187–189.

— Sutton SR, Russell MA, Iyer R. Feyerabend C, Sallojee Y. *Relationship between cigarette yields, puffing patterns, and smoke intake: evidence for tar compensation*? Brit. Med. J., 8/28/82;285: 600–603.

— Wald NJ, Boreham J, Bailey A. *Relative intakes of tar, nicotine, and carbon monoxide from cigarettes of different yields*. Thorax 1984;30:361–364.

— Goldfarb T, Gritz ER, Jarvik ME, Stolerman IP. *Reactions to cigarettes as a function of nicotine and "tar."* Clin. Pharmacol. 7her. 19(6):767–772.

— Maron DJ, Fortmann SP. *Nicotine yield and measures of cigarette smoke exposure in a large population: are lower-yield cigarettes safer?* AJPH 5/87;77(5):546–549.

— Stepney, R. *Consumption of cigarettes of reduced tar and nicotine delivery*. Brit. Addiction. 1980;75:81–88.

— Grunberg NE, Morse DE, Maycock VA, Kozlowski LT. *Changes in overwrap and butt length of American filter cigarettes. An influence on reported tar yields*. N. Y. State J. of Med., 7/85:310–312.

Directive. If a new system of measuring nicotine is needed, please give your specific recommendations for a more accurate methodology.

Response. Although FDA is aware of methods for assessing tar and nicotine yield that more closely approximate actual nicotine exposure to smokers, the Agency is not presently in a position to recommend any one methodology, nor is FDA aware of a consensus in the scientific community as to any one methodology. In light of concerns with the accuracy of the current method held by FTC, FDA, the Congress, and members of the scientific community, and the lack of consensus as to alternatives, FDA fully supports NCI's plan to evaluate the accuracy and relevance of the FTC method in a scientific forum. It is the Agency's position that sound science should be the cornerstone of any consensus building that would underlie regulatory decisionmaking on this issue.

ESTABLISHING A NICOTINE THRESHOLD FOR ADDICTION

THE IMPLICATIONS FOR TOBACCO REGULATION

On February 25, 1994, the Food and Drug Administration (FDA) released a letter to the Coalition on Smoking or Health announcing its intention to consider regulating cigarettes. The Agency's premises were that the vast majority of tobacco users self-administer the product for the drug effects of nicotine and to sustain addiction and that cigarette manufacturers control the levels of nicotine in cigarettes to maintain this addiction. The FDA further raised the possibility of regulating cigarettes on the basis of their nicotine content to prevent addiction.

On February 28, 1994, the ABC news program *Day One* presented evidence that tobacco manufacturers manipulate the nicotine content of cigarettes. One way they do this is by removing nicotine from tobacco and then adding it back in controlled amounts, using tobacco extracts containing nicotine. It was suggested on the news program that the amount of nicotine in tobacco was controlled to ensure that the level was adequate to maintain nicotine addiction. In support of this idea the program quoted an internal memorandum from a Philip Morris Tobacco Company scientist that had been discovered in recent litigation: "The cigarette should be conceived not as a product but as a package. The product is nicotine . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke."[1] That the pharmacologic actions of nicotine are important determinants of why people smoke is supported by studies conducted by the tobacco industry[2,3] and by nonindustry researchers.[4]

That nicotine addiction sustains tobacco use for most smokers is well established.[4] Once a person is addicted to nicotine, quitting smoking is difficult, and more than 90 percent of the smokers who try to quit each year fail.[5] An important, if not the most important, component of a policy to reduce tobacco use in the population is to prevent the development of nicotine addiction in young people.[6] Young people do not start to smoke because they are addicted, but rather because of psychosocial and environmental influences, particularly peer influences, psychological factors, and advertising. Young people generally underestimate the addictiveness of nicotine, and most of them at first intend to smoke only for a few years.[6] However, once they begin to smoke, many become addicted to nicotine, and this addiction sustains the self-injurious behavior into adulthood. The result of nicotine addiction is a 40 percent probability of premature death from illness caused by tobacco.[7] It is difficult to prevent adolescents from experimenting with cigarettes. However, by regulating the availability of nicotine in tobacco products, it may be possible to prevent the transition from experimental or occasional smoking to addiction. This paper examines the proposition that the level of nicotine likely to produce addiction can be estimated and that mandating a nicotine content below that level is a feasible approach to tobacco regulation.

IS THERE A THRESHOLD LEVEL OF NICOTINE INTAKE ASSOCIATION WITH ADDICTION?

We define addiction according to the *Surgeon General's 1988 Report on Nicotine Addiction*: it is the compulsive use of a drug that has psychoactivity and that may be associated with tolerance and physical dependence (*i.e.*, may be associated with withdrawal symptoms after the cessation of drug use).[4] For smokers, addiction is assumed to involve daily smoking of cigarettes, difficulty in not smoking every day, and a high likelihood of withdrawal symptoms after cessation of smoking.

Most Americans smokers are believed to be addicted according to these criteria.[8] However, approximately 10 percent of current smokers (a group sometimes called tobacco "chippers") regularly smoke 5 or fewer cigarettes per day and appear not to be addicted.[9] Most do not have withdrawal symptoms when they stop. Typically, such people smoke in specific situations, can skip smoking for one or more days, and can quit smoking without great personal distress.

The daily intake of nicotine from tobacco can be estimated from the level of cotinine, the principal metabolite of nicotine, in blood or saliva.[10] The average blood cotinine concentration in addicted smokers is about 300 ng per milliliter.[11,12] Smokers of 5 or fewer cigarettes per day have average serum cotinine levels of 54 ng per milliliter and an average consumption of 3.9 cigarettes per day.[13] The cotinine level normalized for cigarette consumption is 14 ng per milliliter per cigarette, or 70 ng per milliliter for a person who smokes 5-cigarettes-per-day. Thus, it is reasonable to estimate a level of 50 to 70 ng of cotinine per milliliter as a cutoff point for the addictive threshold. Of course, there is no sharply demarcated threshold level and there are some people who smoke fewer than five cigarettes per day and have great

difficulty in quitting and others who can smoke more than five cigarettes per day and quit with ease.

Studies involving the infusion of nicotine and cotinine into smokers indicate that the daily intake of nicotine can be estimated as 0.08 times the blood cotinine per milliliter corresponds to a daily intake of 4 to 6 mg as a threshold level that can readily establish and sustain addiction.

DELIVERY OF NICOTINE FROM CIGARETTES

On average, an American cigarette contains 8 to 9 mg of nicotine.[11] The concentration of nicotine in tobacco ranges from 1.5 to 2.5 percent.

Typically, the cigarette delivers about 1 mg of nicotine to the circulation of the smoker,[14] representing an absolute bioavilability of about 12 percent. The variation in intake per cigarette is considerable, however, ranging from 0.3 to 3.2 mg, representing a bioavailability of 3 to 40 percent, depending on how the cigarette is smoked.[14 15] The daily intake of nicotine is poorly correlated with machine-determined yields.[11 12 16] This is because smoking machines smoke cigarettes in a standardized way, whereas people can take more puffs, puff more intensively, and occlude ventilation holes in the filter or on the cigarette in order to obtain the desired dose of nicotine from most cigarettes. When the number of cigarettes available to an individual smoker is reduced from an average of 38 to 5 per day, the intake of nicotine per cigarette increases an average of threefold,[17] a figure consistent with the maximal absolute bioavailability is the percentage of the nicotine contained in the cigarette that can be absorbed systemically by the smoker; it is unrelated to the smoking-machine yield. If the design of cigarettes were to change, bioavailability would need to be reassessed in people smoking the redesigned cigarettes.

THRESHOLD LEVELS OF NICOTINE IN CIGARETTES AS A WAY TO AVERT ADDICTION

Although machine-measured cigarette yields are not useful in predicting a smoker's intake of nicotine, the absolute level of nicotine in a cigarette could be regulated to limit the maximal obtainable dose. Studies using cigarettes developed for research purposes to be low in nicotine have demonstrated that intake can be limited by restricting the amount of nicotine in the tobacco.[2 18]

Assuming that the estimated target daily dose of nicotine should be 5 mg or less to avert addiction and that a young person may smoke up to 30 cigarettes per day, one can conclude that a maximal available (*i.e.*, systemic) dose of 0.17 mg of nicotine per cigarette is the threshold level for a less-addictive cigarette. Assuming a maximal bioavailability of 40 percent with intensive smoking, an absolute limit of 0.4 to 0.5 mg of nicotine per cigarette should be adequate to prevent or limit the development of addiction in most young people. At the same time, it may provide enough nicotine for taste and sensory stimulation.

A POSSIBLE STRATEGY FOR REGULATION

The rationale behind the strategy for regulating the nicotine content of cigarettes is to prevent the development of nicotine addiction in young people. To minimize the hardship to already addicted adult smokers, the level of nicotine in tobacco could be reduced gradually, with a goal of reaching a target nicotine level over perhaps 10 to 15 years. The intended result of such a strategy would be that cigarettes could still be sold, but the number of addicted smokers would be markedly reduced. In the absence of addiction, levels of tobacco consumption should decline sharply, causing a substantial reduction in the rates of tobacco caused illnesses.

There are, of course, a number of caveats. A threshold-old level for nicotine addiction is a theoretical concept based on observations in current smokers and studies of the bioavailability of nicotine during smoking restriction. That restricting levels of nicotine would prevent addiction needs to be verified empirically. There is concern that for already addicted adult smokers, reducing the nicotine level in tobacco might result in more intensive compensatory smoking, with increased exposure to toxic combustion products such as carbon monoxide and tar. Switching from higher-yield to lower-yield cigarettes has been shown to result in smoking more cigarettes or smoking more intensively, both of which are associated with increased exposure to carbon monoxide and other toxins.[18 19] Overcompensation (*i.e.*, inhaling more smoke from low-nicotine cigarettes than from higher-yield brands) appears, however, to persist only for days or weeks. In long-term studies of carbon monoxide exposure after subjects switched to low-yield cigarettes, compensatory oversmoking appears not to persist.[20 21] It is also conceivable that cigarettes could be manufactured to reduce the delivery of tar and carbon monoxide as well as the nicotine content. Even if there is some element of overcompensation and smokers are exposed to increased

levels of toxins, their short-term (10-year) risk may be offset by the long-term benefit of a greater likelihood that they will stop smoking (as cigarettes become less satisfying) and by the enormous benefit of preventing nicotine addiction in future generations.

It should be noted that other researchers have proposed the introduction of "safer" cigarettes that are enriched with nicotine in order to reduce the ratio of tar to nicotine.[22] The rationale for such cigarettes is that smokers would need to inhale less smoke to obtain the desired dose of nicotine, and exposure to toxins would thus be reduced. A strategy involving nicotine-enriched cigarettes might reduce morbidity and mortality from cigarette smoking, but the reduction would probably be limited, because even at reduced doses, tobacco smoke is highly toxic. The goal of that approach—producing a safer cigarette for those who cannot stop smoking—is the diametric opposite of ours. Our goal is the prevention of nicotine addiction and a reduction in the prevalence of cigarette smoking, which in the long term would eliminate exposure to the toxins in tobacco smoke and reduce tobacco-induced morbidity and mortality much more.

The measures described in this proposal may seem drastic to some. However, the problem of one quarter of a billion premature deaths caused by the tobacco use in developed countries[7] calls for drastic action. Tobacco use is motivated by nicotine addiction. We offer a strategy for the prevention of nicotine addiction based on recent scientific data. This approach deserves study by the regulatory authorities.

We are intended to Dr. Charles R. Schuster, former director of the National Institute on Drug Abuse and Dr. John Slade, University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, for their helpful comments; and to Ms Kaye Welch for assistance in the preparation of the manuscript.

Address reprint requests to Dr. Benowitz at San Francisco General Hospital, Bldg. 30, Rm. 3220, 1001 Potrero Ave., San Francisco, CA 94110.

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LETTERS

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Washington, DC., August 4, 1994.

Hon. THOMAS A. DASCHLE,
U.S. Senate, Washington, DC.

DEAR SENATOR DASCHLE: This letter is in response to my promise at the July 28, 1994 hearing, to provide you with additional information and perspective on the question of the theoretical maximum residue contribution (TMRC) exceeding EPA's safety standard (commonly known as the Reference Dose) (RfD).

Research has shown that use of the TMRC (exposure to residues at the tolerance level on 100 percent of the food for which a tolerance has been established) has been shown repeatedly to overstate the risk by many orders of magnitude. Also, in most cases where the TMRC exceeds the RfD, the use of actual or anticipated residues, combined with percent crop treated, demonstrates no exceedance of the RfD. (Please see the enclosed Fisher letter for documentation). There are many pesticides where the TMRC is only a small fraction of the RfD. (*See* the enclosed Fisher letter and Table 3 in the Winter article).

Dr. Winter also points out that creating a new tolerance system (as the Clinton administration has proposed in their legislation) for fresh and processed food at the retail level will not provide an increase in public health protection over and above the current system. We agree that our food is already safe. Such a scheme would not make it any safer.

You also asked me to provide you with the definition of negligible risk which we support. The enclosed language is taken from S. 1478, The Food Safety Act of 1993, introduced by Senators Pryor and Lugar and cosponsored by 20 additional Senators.

We would be happy to discuss the enclosed material with you and your staff. We would also be happy to arrange for Dr. Winter to elaborate on his research on food safety. We also request that this letter and enclosures be entered into the record of the July 28th hearing.

Sincerely,

JAY J. VROOM.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 30 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Honorable Edward M. Kennedy
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for your letter of February 19 requesting a list of all food-use pesticides comparing the Theoretical Maximum Residue Contribution (TMRC) to the Reference Dose (RfD) for all consumer groups, including children. In responding to your letter, we believe it is important to put this information in context. As we explain below, simply comparing the TMRC and the RfD can be seriously misleading. Therefore, we have tried to supply not only the information you requested, but also additional data that lend perspective to the extent of dietary exposure to pesticides.

Enclosed is a list of food-use pesticides comparing the TMRC to the RfD for the general population and each of the population subgroups in the Environmental Protection Agency's (EPA's) Dietary Risk Evaluation System (DRES) (see Table 1). The numbers in this table represent the theoretical dietary exposure estimate as a percent of the RfD (i.e., TMRC/RfDx100%). Both the TMRC and RfD are calculated in units of milligrams per kilogram of body weight per day. As you can see, infants and children are the two subgroups that typically receive the most exposure to pesticide residues in the diet as a percentage of body weight. The estimated residue contributions for the other subgroups are almost always close to the estimates for the general population.

A number of pesticides on the enclosed list have TMRCs which exceed their RfDs. The Agency uses TMRC/RfD calculations to flag chemicals which should receive closer regulatory scrutiny because dietary exposure appears to exceed acceptable levels, but, for several reasons, the Agency does not believe that TMRC exceedance of an RfD is an indication of actual risk. As has been shown repeatedly, the TMRC greatly overstates dietary exposure to pesticide residues. In calculating the TMRC, EPA assumes that the pesticide is present on 100% of each crop for which it has a tolerance. We also assume that residues on the consumed commodities are at the tolerance levels. In reality, these two assumptions are rarely true. Often, only a relatively small percentage of crops are treated, and actual pesticide residues on food at the dinner table are usually much lower than tolerance levels.

While we recognize that the TMRC greatly overstates dietary exposure, we think that there is a use for TMRC calculations. Since a TMRC is clearly an upper limit on exposure and it can be quickly and easily calculated, we use the TMRC/RfD comparison to evaluate whether there is any possible dietary concern. If the TMRC is below the RfD, we can be certain that actual dietary exposure is far below any level of concern. In such an instance, determining the actual exposure level would be wasteful of scarce Agency resources. On the other hand, if the TMRC exceeds the RfD, some further consideration of dietary exposure may be appropriate, as discussed below.

In numerous cases involving TMRCs which exceed the RfD, EPA has developed more refined dietary exposure estimates which are based on reliable information on levels of residues anticipated in food, and which more closely approach actual human exposure to pesticides in the diet. Enclosed is a table with refined percent of RfD calculations (Table 2) for food-use pesticides based on available anticipated residue (AR) data (e.g., data on the percentage of crops to which the pesticide is applied, residue monitoring data and field trial data). As you can see, when we factor in these additional data, we obtain dietary exposure estimates that are 10's or 100's of times lower than the TMRC. As the Agency receives and reviews additional residue data during the reregistration process, we will be able to make more realistic estimates of pesticide residue levels in food.

[NOTE: Six pesticides at the bottom of Tables 1 and 2 do not have accurate RfD exceedance numbers for a number of other reasons: EPA has not established RfDs for flucythrinate and isofenphos; the numbers for methyl bromide are inaccurate because the RfD is based on effects from exposure to methyl bromide, while the tolerances are established for residues for the bromide ion; and the values for the EBDCs (metiram, maneb and mancozeb) do not reflect the Agency's recent regulatory action to cancel some food uses for these chemicals.]

Even in the absence of anticipated residue data, we know that many of the TMRC calculations in Table 1 overstate actual exposure to pesticide residues in the diet. Several pesticides on the list are no longer registered in the U.S. and are scheduled to have some or all of their tolerances revoked. We have enclosed a list of those pesticides which have had some or all food use registrations canceled (Table 3a). Also enclosed is a list of pesticides which are expected to have some or all tolerances revoked in 1992 (Table 3b). Although we have identified these chemicals for you, we have not yet updated the DRES system to account for many of these canceled pesticide uses and revoked tolerances. In addition, many of the TMRC and AR calculations (Tables 1 and 2) include pesticide uses which have import tolerances but no corresponding U.S. registration. For pesticides with import tolerances, TMRC calculations do not account for the fact that some imported commodities may make up only a small percentage of consumption in the United States. Finally, in some cases the TMRC calculations include residue levels from temporary pesticide uses under emergency exemptions that may no longer be in effect.

The enclosed information also tends to overstate the dietary risks for pesticides because of EPA's conservative approach in calculating RfDs. To establish an RfD, EPA scientists evaluate toxicity data to identify the highest level of exposure which did not cause any effect in any of the tests. This is called the "No Observed Effect Level," or NOEL. The Agency then divides the NOEL by an uncertainty factor, usually 100, to calculate the RfD. The uncertainty factor is intended to allow an extra margin of safety to compensate for (1) the scientific uncertainty inherent in the process of extrapolating potential human responses from animal data, and (2) the possibility of differing sensitivities to a pesticide in individuals or subgroups (such as children) among the general population. When EPA has a complete toxicology data base on which to base the RfD, the uncertainty factor reflects a 10-fold margin of safety for each of these two factors, resulting in a 100-fold margin of safety.

In cases where EPA does not have a complete toxicity data base, a larger, provisional uncertainty factor -- usually 300 or 1,000 -- is used to calculate the RfD. We have identified the chemicals whose RfDs were calculated using a provisional uncertainty factor (see Table 4). Those chemicals with incomplete data bases are marked with a "P" (for Provisional Acceptable Daily Intake or PADI) or an "L" (for Provisional Limiting Dose or PLD). It is the Agency's experience that completing a chemical's toxicity data base usually reduces the exceedance. As we receive and review additional toxicity data in our reregistration program, we will be able to update the RfDs and the enclosed DRES calculations for food-use pesticides.

EPA's RfD Exceeders Project

While TMRC calculations overstate dietary exposure, EPA has used RfD exceedance based on TMRC calculations to help determine the need for additional dietary exposure analyses and regulatory decisions. Several years ago, EPA recognized that RfD exceedance posed a concern, and we initiated a project to take a closer look at some of the highest apparent RfD exceeders. The Agency selected chemicals that had significant apparent RfD exceedances based on TMRC calculations, had fairly complete data bases, had not been canceled, and were not being examined in another system such as the Special Review process. Using these criteria, we narrowed the list down to ten pesticides. Using limited available data on the percent of crops on which the pesticides are used and anticipated residues, we calculated more accurate dietary exposure estimates for these pesticides. For most of these new estimates, the calculation reflected a combination of both anticipated residue values and TMRC values for those crops lacking reliable and readily available data. After conducting these analyses (which, thus, still overstated exposure), seven out of the ten pesticides were found not to exceed their RfDs. The RfD exceedances for two other pesticides were reduced dramatically, and we expect that additional residue data will indicate that total dietary exposure estimates for these two pesticides, which still exceed their RfDs, will be below their RfDs. For example, the latest calculations for endosulfan (one of the two chemicals) are based on an assumption

that all tea consumed in the United States is imported from India and is treated with endosulfan (to account for an import tolerance for endosulfan used on dried tea from India). Even though we know that only some of the tea consumed in the United States comes from India (and a smaller amount will have been treated with endosulfan), until we can quantify these factors, we will not revise our dietary exposure calculations for endosulfan to reflect these factors. The import tolerance for tea contributes heavily (roughly 60%) to the current estimate of dietary exposure to endosulfan. We are still reviewing additional data on the last pesticide in the pilot project (diazinon), and we expect to complete this analysis soon. More detailed results of the Agency's analyses to date for the ten chemicals in the pilot project are in the table below:

Pesticide	Starting % of RfD Using TMRC Calculations	% of RfD After Factoring In % Crop Treated and/or Anticipated Residue Data
Dimethoate	6377%	45%
Diuron	518%	27%
Endosulfan	2421%	242%
Fenitrothion	942%	19%
Malathion	499%	57%
Methyl Parathion	4049%	262%
Naled	523%	28%
Parathion	636%	30%
Profenofos	665%	8%
Diazinon	8304%	incomplete

While the RfD pilot project does not answer every question about all RfD exceeders, it does tell us that more realistic estimates of exposure obtained by using anticipated residue information generally results in non-exceedance of the RfD. Therefore, we believe that in most cases our resources would be best directed toward reviewing most RfD exceedance issues during reregistration. EPA expects to receive much of the data needed to reevaluate tolerances and dietary exposure estimates for food-use chemicals in the reregistration process.

In addition to the exceedance project, EPA uses RfD exceedance based on TMRC calculations as a basis for regulatory decisions on new food uses. Under the Registration Standards program (1984-88), when we found chemicals whose TMRCs greatly exceeded the RfDs, we made decisions not to allow significant new food uses until we either received more data to show that actual dietary exposure was below the RfD or the registrant voluntarily canceled other food uses to reduce overall dietary exposure. EPA defines a "significant new food use" as any food use that would increase the TMRC by 1% or more. We have enclosed a list of chemicals from the Registration Standards program where EPA instituted a "no significant new use" policy (Table 5). This policy continues to apply to chemicals subject to reregistration. In addition, for chemicals not subject to reregistration, we will not issue a tolerance for a significant new food use if the TMRC exceeds the RfD and we do not have the data to make an anticipated residue calculation that shows exposure to be below the RfD.

Finally, some of the pesticides on the enclosed tables are being evaluated in EPA's Special Review process. Enclosed is a list of chemicals currently in the Special Review process (Table 6). We will be reviewing the dietary risks of these chemicals as part of the Special Review.

Since TMRC estimates can be very misleading, the apparent RfD exceeders on the enclosed tables should not be a cause for alarm. As explained above, TMRC values overestimate actual dietary exposure to pesticide residues. The latest results of the Agency's RfD exceeders project confirm this conclusion. However, the TMRC/RfD comparison is a useful guide to help the Agency determine the need for additional regulatory decisions or dietary exposure analyses.

If I may be of further assistance, please let me know.

Sincerely yours,

Linda J. Fisher

Linda J. Fisher
Assistant Administrator

Enclosures

FOODSAFE PROGRAM,
Davis, CA, July 18, 1994

Ms. Christine L. Gillis,
U.S. Environmental Protection Agency, Office of Pesticide Programs, Policy and Special Projects Staff (7501C), 401 M Street SW., Washington, DC.

DEAR MS. GILLIS: Thank you for soliciting my comments on the EPA's preliminary proposal to "reinvent" the process for establishing pesticide tolerances. I am Dr. Carl Winter and I direct the FoodSafe Program of the University of California at Davis in addition to serving as Associate Extension Food Toxicologist in the Department of Food Science and Technology. My research and outreach activities have focused upon the scientific, regulatory, and policy aspects of food safety with respect to pesticides; I have published numerous technical and lay articles on the subject and have twice presented invited Congressional testimony. In my 7 years as a faculty member at the University of California I have not received any program funding from the agricultural, chemical, or food industries.

From the proposal's executive summary, it appears that the major goal of the proposed changes is to elicit public confidence in the protectiveness of the food supply by improving public health protection and by making the tolerance setting system easier to understand. While the document reads well and incorporates several interesting ideas, I remain skeptical that adoption of the proposed changes would provide any increase in public health protection. In addition, the processes described to "reinvent" tolerances would seem to make the system more difficult to understand.

A central premise of the proposal seems to be that creating new tolerances for processed foods and at the retail level, coupled with reducing some tolerances for raw agricultural commodities, will provide additional consumer protection from pesticides. From a theoretical standpoint, this can be shown to be the case since the TMRC (or TMDI) would be lowered. In the real world, however, such changes to the tolerances would not result in any decrease in consumer exposure to pesticides since the changes are unlikely to affect pesticide use patterns. (This issue is described in more detail in a recent article [C.K. Winter, *Pesticide tolerances and their relevance as safety standards*, Regulatory Toxicology and Pharmacology, 15: 137–150, 1992]). Thus, pesticides will continue to be used as they have been in the past, and residue levels will therefore be unaffected. It may be argued that enforcement of the new and/or lower tolerances could lead to a greater percentage of illegal residues and seizure of offending food samples would decrease consumer exposure to such residues. From a practical standpoint, however, given the low anticipated incidence of over-tolerance residues, the low sampling rates, and the difficulty in preventing illegal residues from reaching the consumer, the health benefits to consumers from more rigorous enforcement of the new tolerances would be negligible and certainly would not justify the expense of additional monitoring of different food forms.

The procedures described for the establishment of tolerances for processed and retail foods imply that accurate data exist to demonstrate the effects of postharvest factors such as washing, peeling, cooking, canning, transportation, etc. upon pesticide residue levels. While some data do exist, it is my impression that a majority of data is lacking when one wishes to consider such postharvest effects on specific pesticides and specific processed and retail food items. Generation of such data would be expensive, time-consuming, and of little actual value to consumers given the insignificant impacts on consumer exposure to pesticides if the new tolerances are established.

The new tolerances would serve to provide additional confusion, rather than clarification, to consumers, food producers, and food processors by making an already complicated regulatory system even more difficult to understand. The new tolerances could also have ramifications to international trade and could possibly be viewed as nontariff trade barriers which could trigger retaliation on the parts of U.S. trading partners through adoption of new standards that would discriminate against U.S. products.

The major problem with both the existing and proposed tolerance setting systems is the reliance upon the TMRC (TMDI) approach for estimating consumer exposure. As is pointed out in the proposal, such an approach yields highly exaggerated exposure estimates and fails to take into account the actual residues consumed. Just as the inflexibility of the Delaney clause has led to irresponsible regulation of pesticides, continued and prescribed use of TMRCs and TMDIs as regulatory tools will ensure that pesticide tolerances will not be health-based and may provide obstacles to the safe and effective use of pesticides which are not justified by scientific concerns.

It is apparent that the procedures described for "reinventing" pesticide tolerances were crafted to justify continued regulation of pesticides for which the existing

TMRCs exceed the reference doses or provide an oncogenic risk of greater than 10^{-6}. As such, I consider the procedures mathematical manipulations designed to enhance consumer confidence and satisfy the National Academy of Sciences' recommendation that tolerances be more "health-based" rather than as blueprints for serious efforts to enhance the safety of the food supply.

It is not necessary to "reinvent" tolerances. As is mentioned in the proposal, techniques already exist to determine EMDIs and EDIs which incorporate realistic residue, pesticide use, and postharvest data. It is these exposure estimates that EPA should use to determine if consumers are protected from pesticide residues. If the EPA concludes that adequate protection exists, tolerances should be established at the field level necessary to ensure adequate pest control, as is currently the case. Replacing these more accurate exposure estimates with an unrealistic mathematical construct such as the TMDI serves no practical purpose but unnecessarily increases bureaucratic burdens and complicates an already confusing process.

While I do not support your proposal to "reinvent" pesticide tolerances, I am supportive of some of the proposed changes. Changing the terms "tolerances" and "Theoretical Maximum Residue Contribution" to "Maximum Residue Limits" and "Theoretical Maximum Daily Intake," respectively is certainly warranted. I also applaud your efforts to reanalyze the residue field trial data used to establish the tolerance on raw agriculture commodities to eliminate the effects of "outliers" on the tolerance levels. In some cases, the tolerances are probably far greater than they have to be to ensure that growers using pesticides properly can be in compliance; it is also likely that improper pesticide use may not result in illegal residues in cases where the tolerances have been skewed due to the presence of "outliers."

Thank you for providing me with the opportunity to comment upon your proposal. I agree that the processes for regulating pesticide residues are enormously complex and difficult to explain to the general population, since tolerances are truly not health-based but represent enforcement tools designed to determine if pesticide applications have been made in accordance with label directions. To clarify the issue, I am currently preparing a manuscript for publication in *Regulatory Toxicology and Pharmacology* proposing a new system for establishment of "safety" standards for pesticide residues as companions to the existing enforcement tolerances (or MRLs). Such an approach could provide the impetus to shift the focus of regulatory monitoring from field enforcement to health enforcement, and could also assist in the interpretation of differences between United States and foreign residue standards and allow the health significance of technical residue violations (*e.g.*, pesticides detected on commodities for which they are not registered) to be determined. I would be pleased to share some of my ideas on this subject with you at your convenience.

Sincerely,

CARL K. WINTER.

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