FOOD QUALITY PROTECTION ACT OF 1995

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

ON

H.R. 1627

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FOOD QUALITY PROTECTION ACT OF 1995

WEDNESDAY, JUNE 7, 1995

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Burr, Bilbray, Whitfield, Ganske, Coburn, Bliley (ex officio), Waxman, Brown, Lincoln, Towns, and Pallone.

Staff present: Mary M. McGrane, majority counsel; Howard Cohen, majority counsel; and Kay Holcombe, minority professional staff member.

Mr. BILIRAKIS. Good morning. I am pleased to call this hearing on H.R. 1627, the Food Quality Protection Act of 1995 to order, and I'm pleased that this bill, introduced by Mr. Bliley and Mr. Towns, enjoys strong bipartisan support.

I would like to announce in advance that since we have a long day ahead of us, with four different panels, I'm going to try to stick to 5-minute rules. Insofar as opening statements are concerned, I will afford 5 minutes to myself and to the ranking member and then 3 minutes to other members of this panel and then go on down to the witnesses.

In 1958 Congress passed the Delaney Clause which establishes a zero cancer risk standard for food additives including pesticide residues. As we are aware from the current court decisions, the Delaney Clause does not allow consideration of whether the cancer risk is negligible, meaning extremely small, or whether there are other beneficial characteristics of the product.

Since the passage of the Delaney clause, science has developed sophisticated methods to detect smaller and smaller residues. For example, today we routinely measure in parts per trillion, so we can find some of these carcinogens in foods even though they are present in such minuscule levels that they pose no hazard whatsoever.

Until recently, the Environmental Protection Agency regulated pesticide residues using a de minimis standard. This standard allowed EPA to avoid applying the terms of the Delaney standard literally when to do so would yield pointless results. In effect, the agency said that pesticide residues at certain levels were harmless.

But because of a court decision, EPA can no longer take a de minimis approach and must strictly enforce the 1958 law. Con-

sequently, today we are in a position where all sides admit that the Delaney Clause must be reformed. This was clearly the position of the National Academy of Sciences which issued a report several years ago which made a convincing case for the necessity and benefits of reforming the Delaney Clause.

The Food Quality Protection Act of 1995 will modernize, I think, our pesticide laws, keep our food supply safe, and permit EPA to take speedier action when the agency decides a hazardous chemical must be taken off the market. By simplifying and strengthening current law, H.R. 1627 will result in less regulation, less bureaucracy at both the Federal and State level, and be less costly to consumers and taxpayers.

I look forward to the testimony and comments of our witnesses today and call upon the ranking member, Mr. Waxman.

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

Our pesticide laws do need reform. The National Academy of Sciences told us that 2 years ago when it released its report on pesticides in the diets of infants and children. The simple fact is, our current system doesn't ensure that the health of our children is adequately protected. Unfortunately, the bill before us is not the kind of reform we need. It is an extreme measure that would substantially weaken protection against pesticides. It is the agricultural lobbyist's dream and potentially the consumer's nightmare.

In this Congress we have seen a deliberate and sickening onslaught on our Nation's food safety laws. Each year thousands of people die from contaminated meat and poultry; millions of consumers are made sick. The Department of Agriculture proposed regulations in February to deal with this health emergency by improving the quality of meat inspections, and how did the House of Representatives respond? We passed legislation imposing a moratorium on the meat safety regulations. We specifically rejected an amendment to exempt these regulations from the moratorium.

Seafood safety is another big problem. Tens of thousands of Americans get sick from eating contaminated seafood each year. The FDA is trying to issue regulations to ensure the safety of seafood. The agency told us that this effort would be delayed by years if we paralyzed the regulatory system by enacting H.R. 9. What was our response? Again we ignored public health and passed H.R. 9 without exempting vital health regulations like the seafood safety regulations.

The bill before us today, H.R. 1627, is another assault on food safety. As drafted, it would virtually repeal the pesticide provisions of the and Federal Food, Drug, and Cosmetic Act, the cornerstone of our food safety laws. It does this by prohibiting EPA from acting under this law until after that agency has taken action under the far looser standards of FIFRA.

I believe we need a balanced bill. If we are going to repeal the Delaney Clause, then we also need to adopt changes that strengthen our food safety laws. For this reason, I'm introducing today new food safety legislation, the Pesticide Safety and Right to Know Act. This bill has three simple provisions.

First, it says EPA must use a common sense test to protect kids. The agency must determine whether a pesticide is reasonably anticipated to harm children. If it is reasonably anticipated that chil-

dren will be hurt, the tolerance cannot be issued. To ensure that sound science is used in making these common sense determinations, the bill directs EPA to follow the recommendations of the National Academy of Sciences. Second, the bill provides that this same common sense test must be used to protect women from breast cancer; and, finally, the bill has a right to know provision.

Because H.R. 1627 would repeal the Delaney Clause, it will become possible for pesticides containing carcinogens to enter the processed food supply. The right-to-know provision says that if the worst of these pesticides is known and probable human carcinogens are used on foods a label notifying the consumer must be put on the food.

Under H.R. 1627, it will be legal for foods like baby foods and apple sauce to be sprayed with known human carcinogens. If our Government won't be allowed to stop this practice, then we need to give consumers the ability to fend for themselves. Consumers ought to have a right to know whether these proven dangerous chemicals have been added to their food. The Pesticide Safety and Right to Know Act will give them that right.

We should have an opportunity to consider whether H.R. 1627 would be improved by amending to it incorporate the policies in this Pesticide Safety and Right to Know Act, and for this reason it is important that this subcommittee schedule a second day of hearings on this matter.

Mr. Chairman, I look forward to working with you on this legislation, but before we pass a bill I hope it will be a balanced one to protect the consumers.

I yield back the balance of my time.

Mr. BILIRAKIS. The gentleman's time has expired. I thank the gentleman.

Mr. Bliley, the chairman of the full committee.

Mr. BLILEY. Thank you, Mr. Chairman. I appreciate your calling this hearing on an issue of importance to all Americans.

The United States enjoys the world's safest most abundant and affordable food supply. Maintaining the wholesomeness, the variety, and the low cost of our Nation's foods is critical. Each year American farmers lose about 30 percent of their harvest to pests, disease, and spoilage even with pesticides. Therefore, it is critical that farmers be allowed to continue using safe and effective crop protection tools. But because of our Nation's outdated pesticide laws, the potential exists for farmers to lose many of the vital crop protection tools they need and for foods to become more expensive to grow and sell, less abundant, and poorer in quality.

This hearing is particularly timely because of recent court decisions involving the Delaney Clause which could prohibit the use of a growing number of chemicals that pose little or no risk of cancer while allowing the Food and Drug Administration and the Environmental Protection Agency no discretion in their food safety policies.

Existing pesticide regulations greatly exaggerate the degree of risk and ignore any benefits to society from the use of safe crop protection tools. We need laws that will give EPA the flexibility it needs to regulate pesticide use as well as ensuring that strong safety standards will remain in place, particularly safeguards for the health of infants and children. The benefits of a diet high in fruits

and vegetables are well documented, but our existing pesticide laws could have the unintended effect of making these foods more expensive and less readily available.

We need to ensure that all American consumers have an adequate, affordable supply of fruits and vegetables and in fact are encouraged to include more fruit fruits and vegetables in their diets. I believe that the bill which is the subject of today's hearing, H.R. 1627, would accomplish many of these objectives.

Mr. Chairman, I applaud you for holding this hearing, and I stand ready to work with you on this important issue. I yield back the balance of my time.

Mr. BILIRAKIS. I thank my chairman.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me begin by thanking you for calling this hearing.

This hearing gives us an important opportunity to begin the process of updating and modernizing our Nation's pesticide laws. As a cosponsor of this legislation for the past two Congresses, I am pleased that we finally appear to be moving forward with a reform measure which will allow the EPA to base its regulation of pesticides on a sound science based assessment of real world risk. H.R. 1627 will replace the outdated Delaney Clause with a flexible standard that makes a risk determination based on modern science and allows the use of substances that pose a negligible risk to public health as recommended by the National Academy of Sciences.

In recognition of the fact that the Food, Drug, and Cosmetics Act should be amended to include specific provisions to ensure adequate consideration of the health of infants and children, this bill grants reasonable discretion to the EPA to determine appropriate safety testing requirements for infants and children. This measure also responds to earlier recommendations that the dual standards for raw and processed food tolerances be replaced with a single science-based standard. That makes sense, and I support it.

Mr. Chairman, I look forward to working with you in trying to strengthen our laws because I think the time has come for us to do that, and I applaud you for moving forward. I look forward to hearing from our witnesses because I think the time has come when we should make these changes.

I yield back.

Mr. BILIRAKIS. I thank the gentleman and wanted to make it clear he not only is a cosponsor of the legislation, he is a chief original cosponsor of the legislation.

Mr. Ganske—Dr. Ganske—3 minutes please.

Mr. GANSKE. Thank you, Mr. Chairman.

I'm very pleased to be a cosponsor of H.R. 1627, the Food Quality Protection Act. This important common sense legislation is long overdue. Although I'm new to Congress, I understand that in the past 15 years Congress has held more than 25 hearings that included testimony that impacted on the Delaney Clause. While there is an extensive record on why this outdated relic needs to be changed, I understand the need to continue to reeducate certain members of the committee on the latest changes in the field of science.

As I said, the Delaney Clause is a relic that is scientifically outdated and should be changed. Since 1977 two National Academy of Science reports have been published that recommended Delaney Clause reform. Following the 1987 NAS report "Regulating Pesticides in Food, the Delaney Paradox," the EPA announced it would incorporate the recommendations of the report. Several groups and individuals, including the National Cancer Institute, the American Cancer Society, the American Medical Association, and former Surgeon General C. Everett Koop, supported changing the existing policy. Unfortunately, the EPA's actions were challenged in court and we find ourselves here today.

The old era of congressional policy by committee command without the complete scientific facts is over. Today's technology and the level of scientific expertise requires us to act. The use of sound science will ensure that our Nation's food safety policy flows from a rational, logical basis. Sound science will also ensure that our Nation's food supply will continue to remain safe.

Carol Browner, the current EPA Administrator, herself stated in a February 1993 New York Times article, "We do not believe that consumption of these pesticides as residues in processed food products is a threat. These foods are safe." Before we hear any horror stories today about Republican efforts to turn back food safety and how this legislation will poison our children, our spouses, and our parents, let me point out that H.R. 1627 has received strong bipartisan support. Nearly 30 members from the other side of the aisle have cosponsored this legislation already. This is a bill about common sense, it is a bill about ensuring safety, and it is a signal that reform has come.

Mr. Chairman, I thank you for your efforts on this issue, and I appreciate your leadership.

Mr. BILIRAKIS. I thank the gentleman, and his time has expired.

Mr. Brown, 3 minutes please.

Mr. BROWN. Thank you, Mr. Chairman.

It is good to see George Orwell is back in front of our committee. First the Republican leadership opposes an increase in the minimum wage and they call it the Job Creation and Wage Enhancement Act. Then the Republicans propose lowering the earned income tax credit and they call that the American Dream Restoration Act. Then they refuse to take Social Security off budget in the balanced budget amendment and call that the Senior Citizens Fairness Act. And now that they are moving forward in their typically extreme way on food safety issues and pesticide issues, they call that the Food Quality Protection Act of 1995. That kind of Orwellian thinking is frankly what makes people cynical about this process, about this Congress, about this new majority.

I agree that the Delaney Clause needs reform. I think we can move forward in doing that. But it doesn't mean rolling back the kinds of food safety and health laws around which this society has built a consensus.

Just recently Government, over the opposition of the food industry year after year after year, put nutrition labeling on virtually every food item you buy in the grocery store. I think every one of us knows more about dietary fiber and more about fat and more about sodium when you pick up a can of soup at the grocery store

and you look at this brand and that brand, and how much sodium, and how much dietary fat, and how much sugar content, and in all of nutrition labeling that the food industry opposed that government finally was able to do to get more information into consumers' hands, that same kind of move, when government can be involved and can help to build a consensus on making the air cleaner and the water safer and our food purer, only makes sense.

I represent an area of Ohio which has some of the highest breast cancer rates in the country and some of the highest prostate cancer rates in the country, and I represent an area where a lot of pregnant women gave birth to babies with birth defects because it was attributed in one major study over the last many years to consumption of large amounts of fish from Lake Erie, and I don't want to see us move in the wrong direction. I think we need to reform the Delaney Clause, but this Orwellian double speak and calling this the Food Quality Protection Act just begs the question a little bit too much, Mr. Chairman.

Thank you.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman.

I'm just going to commend the chairman for bringing this measure to the committee for consideration. I think it is a balanced approach that looks after the benefit of the farming community which is vital to this Nation's economy, as well as display our concern for the safety of children and citizens across the country. So, I commend the chairman and look forward to the hearing.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bilbray.

Mr. BILBRAY. Mr. Chairman, I appreciate the chance to be able to participate in this process.

As a cosponsor, my interest is not in the protection of those who may use certain products for the production of agricultural activities. My concern here comes from a background of over a decade of trying to protect the public health for a population larger than the State of Kansas, and though some of our colleagues may feel that overregulation or regulation cannot be overdone from a public health point of view, let me assure my colleagues that there is a major, major threat to the public well-being by not having regulations based on science. Too often, there has been in the past this concept that if we overregulate we will still have an added safety factor. Well, that same mentality was used by a boy who cried wolf again and again and again, and we all know what happened to that boy.

My concern is that we need to get the science base when we make these evaluations, because it is not just the credibility of those of us who are Members of Congress but the credibility of the entire system that warns our consumers of potential problems. As somebody who comes from a public health background, the credibility of our warnings have been systematically destroyed by irresponsible use of the warning system, and California probably ranks highest, Mr. Chairman, in that. We have posted that anything and everything may have a potential problem, and thus the public refuses to acknowledge that a warning carries any weight any more.

So I would say to my colleagues who point out that they want to protect the public health that we not only have a right, we have a responsibility to make sure that when we post a warning that it is based on science. We should not be confused with the belief that somehow an overreaction creates an element of safety.

When a citizen reads a warning, they need to know that that warning is based on science so that they can take it with some credibility, and believe in what we as people in government have asked to be posted. If not, all the warnings that we place out there have no credibility with our citizens. I think that that is the issue here, that our warnings do bear science so our citizens can feel comfortable with the fact that when they see a warning it is appropriate, rather than what we have seen more and more, especially in my home State where they don't even bother to consider a warning because it has no credibility with the average citizen.

Mr. Chairman, I appreciate this chance to participate, and for the public health, I look forward to moving this legislation.

Mr. BILIRAKIS. I thank the gentleman for his opening statement based on his own personal grassroots experience in the State of California.

Mr. Burr, 3 minutes please.

Mr. BURR. Mr. Chairman, I would ask unanimous consent to put my opening remarks in the record.

Mr. BILIRAKIS. Without objection.

Mr. BURR. I find myself cramming a piece of paper once again from a Federal agency on testimony that we had hoped to get 48 hours in advance only to receive it a little over 12 hours in advance, and I hope, Mr. Chairman, that in the future we will stress this because it seems that every agency of the Federal Government that comes in puts us in a situation where we have absolutely no idea what their remarks or their testimony is going to be.

I yield back.

Mr. BILIRAKIS. I thank the gentleman.

[The prepared statements of Hon. Richard Burr and Hon. Fred Upton follow:

PREPARED STATEMENT OF HON. RICHARD BURR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Thank you, Mr. Chairman.

I appreciate this opportunity to work with my colleagues toward repealing an antiquated regulation which has long since outlived its effectiveness.

Mr. Chairman the repeal of the Delaney Clause follows the precedent that this committee has established throughout the 104th Congress. H.R. 1627 attempts to invoke common sense along with some sound science in the determination of pesticide safety. It takes into consideration the risk/benefit analysis that this committee helped establish this year, while keeping in mind the end goal of producing a safe, adequate, wholesome and economical domestic food supply. In a nutshell, under this bill, everyone wins.

As an original cosponsor of H.R. 1627, I look forward to the expeditious consideration of this bill, which keeps modern technology from becoming a hindrance to successful food production. By setting one tolerance standard for pesticide residues in both raw and processed food, and by basing it on the risk to humans rather than laboratory rats, we are codifying the long awaited step that even the EPA has attempted to take—replacing the Delaney Clause with a negligible risk standard that makes good sense.

Thank you to all of our witnesses. I look forward to the insight you have to offer on this timely and necessary change to current policy.

PREPARED STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Thank you, Mr. Chairman.

As an original cosponsor of H.R. 1627, Chairman Bliley's *Food Quality Protection Act,* I am glad to see this issue come before the subcommittee today and I look forward to the testimony of our witnesses.

H.R. 1627 is an important step in reforming food safety laws. While the goal of the Delaney Clause is commendable, the science used in forming this 1958 law is obsolete. It is high time to re-examine this issue using the best available science today. I am confident that the *Food Quality Protection Act* makes the needed changes to laws governing pesticides and food safety.

As we work on this important issue that will impact every person living in America, my aim will be to ensure a food supply that remains safe, as well as affordable.

Thank you and I yield back the balance of my time.

Mr. BILIRAKIS. Dr. Coburn.

Mr. COBURN. I have no opening statement, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

That completes, I believe, our opening statements for this morning. We will go then to our first panel, Dr. Lynn Goldman, who is the assistant administrator of the Office of Prevention, Pesticides, and Toxic Substances with the EPA. She is accompanied by Mr. Bill Schultz, an alumnus of the staff of this committee.

It is good to see you again, Bill.

He is the deputy commissioner for policy with FDA. And also Mr. Lawrence Elworth, special assistant for pesticide policy with the Department of Agriculture.

Dr. Goldman, why don't we start with you, and, as I understand it, the gentlemen wish to make brief statements in addition to yours. Why don't we start with you for 5 minutes please.

STATEMENT OF LYNN R. GOLDMAN, ASSISTANT ADMINISTRATOR, OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY WILLIAM B. SCHULTZ, DEPUTY COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION; AND LARRY ELWORTH, SPECIAL ASSISTANT FOR PESTICIDE POLICY, DEPARTMENT OF AGRICULTURE

Ms. GOLDMAN. Good morning, Chairman Bilirakis and subcommittee members.

We are pleased to appear before you today to discuss the Food Quality Protection Act of 1995, H.R. 1627. The administration appreciates your interest in reforming our pesticide and food safety laws to ensure that they provide consumers with a safe, abundant, and affordable food supply and allow for advances in science.

As you know, the administration proposed comprehensive pesticide reform legislation in the last Congress amending both FIFRA and FFDCA, legislation that was developed in coordination between FDA, EPA, and USDA. While I understand that amendment of FFDCA is the primary focus of today's hearing, I will also briefly discuss the FIFRA provisions of this bill.

We must modernize FFDCA in order to establish a single health-based standard for residues in food. This public health standard must take into account potentially sensitive populations, especially infants and children, the most vulnerable members of our society. Sound pesticide reform legislation must also provide the fees required to complete reregistration mandated by Congress to ensure

that pesticide registrations are current with scientific standards of today. Some proposed FFDCA changes may not adequately preserve the food safety safeguards that American consumers expect and deserve.

H.R. 1627 would establish a single negligible risk standard for tolerances for raw and processed foods. Although we agree on the need for single health-based standard, it is unclear how the concept of negligible risk would apply to noncancer risks. We believe that a standard of a reasonable certainty of no harm makes more sense. This does mean a negligible risk for cancer, but it also means that for noncancer effects, birth defects, neurotoxicity, and other effects, we would have a reasonable certainty that none of those effects would result from eating foods that have been legally treated with pesticides. H.R. 1627 would allow risks that exceed a negligible level to continue indefinitely if they were outweighed by the benefits of the pesticide.

We believe that the broadly construed economic benefits language contained in H.R. 1627 is not appropriate in a food safety statute. H.R. 1627 would amend FFDCA to establish a single negligible risk standard for tolerances for pesticide residues in raw and processed foods but would allow risks that exceed a negligible level to continue indefinitely. The administration's proposals for tolerance setting contain additional requirements directly responsive to recommendations contained in the NAS report on pesticides in the diets of infants and children.

While we acknowledge the efforts to collect the information, we need to actually use the information to consider risks to children. That is, we feel it is not enough to just gather the information on children's diets and pesticide residues but we would like to see a requirement that the EPA considers the diets and sensitivities of children in setting tolerances.

We are concerned about the very broad scope of preemption under H.R. 1627 because it extends to State and local statements about the presence of pesticide residues in food like California's Proposition 65, and we believe that the Codex language needs to be clarified to ensure that American standards are not jeopardized. Also, the coordination language in H.R. 1627 between FIFRA and FFDCA could be interpreted to negate all of the FFDCA safeguards, including those aimed at protecting children.

Turning to the FIFRA provisions very briefly, while some of the amendments reflect improvements over previous versions, others would make achievement of public health and environmental goals more difficult than current law. Notably, the cancellation provisions in Title I combine the time-consuming features of both rulemaking and formal adjudicatory hearing procedures. Although it specifies strict time limits, the bill simultaneously makes adherence to these deadlines impossible. For example, provisions limiting hearings to 20 days are unlikely to prove workable.

Also, and even more troubling is the conforming amendment which appears to shift the burden of proof of a pesticide's safety from the manufacturers to EPA not only for cancellation but also for calling in data, and, as I said earlier, we feel that any FIFRA provisions should address the need for renewal of the reregistration fees.

In conclusion, the administration and Congress must work together for common sense reform of our pesticide laws. We need to reach agreement on legislation that will protect health, especially the health of children. If we succeed, we will also maintain and enhance public confidence in the safety of the food supply, provide a predictable environment for the agricultural community, and facilitate the development and adoption of safer, effective pest control technologies.

Thank you again for the opportunity to join you this morning. I'll be pleased to answer any questions.

Mr. BILIRAKIS. Thank you, Dr. Goldman. I'm sorry to cut you off, but during the process of questioning I'm sure you will be able to get more in.

Mr. Schultz, very briefly, a couple of minutes, please.

STATEMENT OF WILLIAM B. SCHULTZ

Mr. SCHULTZ. Thank you, Mr. Chairman. I appreciate the opportunity to testify on H.R. 1627.

As the committee well knows, the Food and Drug Administration is the principal agency charged with ensuring the safety of the food supply, but with regard to pesticides we don't set the allowable limits. The tolerances that regulate the residues that are allowed on pesticides are set by EPA. Our job is to enforce those tolerances, so it is within that context that I want to say a few things about the bill. I would like to address both the enforcement provisions and then just the experience we have in food safety.

We believe that H.R. 1627 is very constructive, and we are very pleased that the subcommittee is holding this hearing, but the testimony will identify the problems that we have with the bill. While doing that, I want to emphasize that we are ready to work with the members of the subcommittee, and we think there is a real opportunity to find common ground here, and to actually move legislation that could have broad support.

Now in terms of the enforcement provisions, I want to just make two points, identify two deficiencies. One is, when EPA approves a pesticide it is essential that a way of detecting the amount of the pesticide on the food also be identified. So if EPA says we are going to allow there to be one part per million or one part per billion or one part per trillion of the pesticide on the food, then when we do our enforcement there has to be a method to ensure that we can identify that. This bill does not have that requirement, and it is one that could be easily added.

Second, there need to be enforcement tools that allow the penalty to fit the violation. Currently the FDA has a sledgehammer and a fly swatter. When there is a violation we can have a criminal penalty or we can send a letter, but we have very little in between. For example, civil money penalties, an in-between penalty, I think would be very useful in terms of effective enforcement.

Now I would like to turn to the substantive standard which is so critical in this kind of legislation.

Mr. BILIRAKIS. Without objection, I'll give you another minute, but try to finish it up, please.

Mr. SCHULTZ. I was told we had 5 minutes, Mr. Chairman.

Mr. BILIRAKIS. Oh, were you told you had 5 minutes?

Mr. SCHULTZ. Yes, I was.

Mr. BILIRAKIS. If you were told you have 5 minutes, you have 5 minutes.

Mr. SCHULTZ. Okay. Thank you.

Mr. BILIRAKIS. So you have another 3 minutes.

Mr. SCHULTZ. Okay. Thank you very much.

The substantive standard is critical, and generally our laws have a health-based standard for food additives, color additives, and animal drugs. That is a standard that works very well, and we believe that it would be useful and very protective of the public health to look at that kind of standard which has worked and is absolutely not being criticized.

In particular, we are concerned about the benefits provision in this bill, which is quite broad. It has no limit on the amount of risk that can be overridden by benefits, and there is no match. Mr. Chairman, you can be the consumer, and maybe you are taking the risk, but my benefit can override that risk, and there is no match there. That is a huge problem.

I'm going to tick off a number of issues. First, the bill would allow the FIFRA labeling provisions to override the food safety provisions in the Food, Drug, and Cosmetic Act.

Second, there is a presumption that appears to allow international standards set by Codex to override the higher U.S. standards set by EPA and Congress.

Third, there is insufficient protection of children.

Fourth, the procedural provisions make it easier to get a pesticide on the market than to take it off and really allow a field day for lawyers in terms of delay.

And, finally, there are no provisions that assist EPA in its review of existing pesticides.

In conclusion, Mr. Chairman, the FDA and the administration are committed to the reform of pesticide laws in a way that works for consumers and for farmers. We believe it is possible to achieve this balance, and we are anxious to work with the committee toward this end.

Thank you.

Mr. BILIRAKIS. I thank you, Bill.

Mr. Elworth, you have 5 minutes.

STATEMENT OF LARRY ELWORTH

Mr. ELWORTH. Thank you. Thank you, Mr. Chairman.

The Department of Agriculture appreciates your efforts and the efforts of the members of your subcommittee to resolve issues of long standing importance to USDA and to the agriculture community as a whole. American farmers have an enormous stake in the debate over food safety and pesticide legislation. Producers need a regulatory system that provides them with safe and effective means to manage pests in an environmentally and economically sound manner.

That system must also account for the fact that pesticides are deliberately used for critical needs over a wide range of crops and growing conditions. In that sense, the regulation of pesticide residues under the Food, Drug, and Cosmetic Act differs from the regulation of other food additive residues.

More than anything else, farmers need a regulatory system that provides assurance to consumers that their products, both fresh and processed, are safe and wholesome. Although agricultural producers are not directly involved in the registration of pesticides or the granting of tolerances, they have found that public controversy and regulatory actions can have serious consequences for their ability to raise and market their crops. The laws that guide the evaluation of pesticides must result in the confidence of consumers that the food they and their families eat is safe. This requirement assumes added importance as our markets become more global. The acceptance of our agricultural products as safe and wholesome in the increasingly important international marketplace also depends on our ability to adopt substantive scientifically based food safety standards.

Mr. Chairman, it is clear that our food safety laws are in need of reform. The Federal Insecticide, Fungicide, and Rodenticide Act needs to be revised to ensure that producers have sufficient pest management tools and to ensure that pesticides receive complete review by current scientific standards. In FFDCA the current and potential impacts stemming from the Delaney Clause and the need to account for pesticide residues in the diets of infants and children are issues that require significant legislative attention. USDA believes that these issues should be addressed substantively and that reform of the statute should reflect the basic concerns of all parties that have a stake in these issues.

Although the authors of H.R. 1627 have made a substantial effort to reform both FIFRA and FFDCA, there remain significant issues that merit additional attention and revision. Those concerns are set out in detail in our written statement. At the same time, we support the provisions for minor use and public health pesticides as well as the efforts to ensure protection for the diets of infants and children.

USDA is particularly heartened to see support for its efforts to collect information on food consumption, pesticide residues, and pesticide use, for the IR4 program for minor crop registrations, and for the major commitment USDA has made to increase adoption of integrated pest management. The President's budget has requested the funds for these programs, and we hope to receive the necessary resources to carry out the work that Congress expects us to accomplish.

The main question before all of us today is whether we can continue to make additional progress in the drafting of legislation. USDA and the administration have clearly stated our interest in working with Congress to craft reasonable, common sense legislation. We are pleased to note that work has already begun with members of the Agriculture Committee to resolve several important issues, and we look forward to working with the members of this committee, as well, in the interest of sound legislative reform.

The issues, Mr. Chairman, before this committee are not new. For virtually everyone in this room the issues have an all too familiar and almost shopworn character. However, we once again have the opportunity to make long overdue reforms which will move us toward meeting the needs of agricultural producers and consumers. Taking advantage of this opportunity will require a significant in-

vestment of time and good faith on the part of every party involved to resolve these long-standing issues. We look forward to working with you in that effort, Mr. Chairman, and with others who have a sincere interest in improving our pesticide laws.

Thank you for your time, and we will be glad to answer any questions you may have.

[The combined statement of Lynn R. Goldman, William B. Schultz and Larry Elworth follows:]

PREPARED STATEMENT OF LYNN R. GOLDMAN, M.D., ASSISTANT ADMINISTRATOR FOR PREVENTION, PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

I. INTRODUCTION

Good morning, Chairman Bilirakis and Subcommittee members. We are pleased to appear before you today to discuss H.R. 1627, the Food Quality Protection Act of 1995. We appreciate your interest in key issues relating to pesticides and food safety, and your dedication to the goal of reforming our pesticide laws to ensure that they reflect current science and provide American consumers with assurance that our food supply is and will remain safe, abundant, and affordable.

The issues addressed in this legislation are complex; some have been before Congress for more than two decades. Many stakeholders are involved. Consensus has been difficult to achieve. The science underlying pesticide risk assessment is continually evolving, but our laws at times do not adequately accommodate scientific advances.

At the same time, it is important to acknowledge that the Administration and Congress have embraced common goals of maintaining and enhancing food safety, and ensuring that the legislative changes we make will allow for future progress in science. These shared goals must be at the core of any pesticide/food safety reform legislation. Although there are many stakeholders with special interests, we must never lose sight of our fundamental purpose: to serve the public and protect public health and the environment from unreasonable pesticide risks. Legislation that embodies that purpose will safeguard our food supply and maintain public confidence in food safety, while ensuring that health and the environment are protected and producers have access to effective pest control technologies.

As you know, the Administration proposed comprehensive pesticide reform legislation in the last Congress, amending both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). FIFRA governs pesticide registration or licensing, including labeling that prescribes conditions under which pesticides may be legally used. FFDCA governs tolerances, or maximum legally permissible levels, for pesticide residues in foods.

We understand the FFDCA amendments in H.R. 1627 are the primary focus of today's hearing since they are under the jurisdiction of this Committee. We share the belief that changes are needed to achieve our goal of a sound, consistent statutory framework for pesticide regulation. We must modernize FFDCA in particular to establish a single, health-based standard for residues in food. This public health standard must take into account potential effects on significant subpopulations, especially infants and children—the most vulnerable members of our society—and reflect the recommendations of the 1993 National Academy of Sciences (NAS) report on *Pesticides in the Diets of Infants and Children.*

Finally, sound pesticide reform legislation must provide the fees required to complete on-going reregistration reviews mandated by Congress in 1988, and to ensure that, in the future, pesticide registrations are kept up to date with studies reflecting current scientific advances.

While the sponsors of H.R. 1627 share many of these goals, some provisions of the bill as currently drafted would actually be more unworkable than current law. Other provisions do not go far enough to achieve needed reforms, or would have perverse, in all likelihood unintended, consequences. The Administration cannot support H.R. 1627 unless significant changes are made.

Our testimony today will highlight key provisions of the pending bill. We hope to work with you, and with your colleagues on the Agriculture Committee, to develop legislation that will advance our common goals and achieve meaningful reform.

II. FFDCA PROVISIONS

While this Committee's jurisdiction focuses on FFDCA proposals, it is clear that there can be no effective pesticide regulatory reform legislation unless both FIFRA and FFDCA are amended. This point was evident to the sponsors of H.R. 1627, and as a result they included substantial FFDCA changes in the bill. We are concerned, however, that these changes may not adequately preserve the food safety safeguards that American consumers expect and deserve.

Standards for Tolerance-setting

H.R. 1627 would amend FFDCA to establish a single negligible risk standard for tolerances for pesticide residues in raw and processed foods, but it is less specific in defining what would qualify as "negligible" and allows tolerances to be set that pose greater than negligible risks. It is also unclear how the concept of "negligible risk" would apply to non-cancer risks.

Under the Administration's proposals, tolerances for pesticide residues in all types of food would be based on a strong, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. This is the standard of that currently applies to many pesticides used in processed foods. This new uniform safety standard would replace the current standards in Sections 408 and 409 of FFDCA and would be the basis for regulating pesticide residues in all types of foods, whether raw or processed.

It is significant that this standard has been used by FDA since 1958 to evaluate the safety of food additives and, since 1960, the safety of color additives, both of which are widely used in processed foods. Over the past 30 years, the regulated industries have complied with this standard which has assured consumers that substances permitted to be used in foods are, in fact, safe.

Further, the Administration believes that the appropriate standard is that tolerances should provide a reasonable certainty that no birth defects, neurotoxicity, or other noncancer effects will result from eating foods that have been legally treated with pesticides. To do this, we apply "uncertainty" or "safety" factors when we are relying on animal data alone. The National Research Council in its report entitled *Science and Judgment in Risk Assessment* endorsed this approach.

Benefits Considerations

Our starting point is that the FFDCA should have a health-based standard applicable to pesticides. Any deviation from that principle should be carefully justified and specifically tailored.

However, H.R. 1627 does not meet this standard. It would allow use of a pesticide which poses a greater than negligible dietary risk, if the dietary risks to the consumer are outweighed by the pesticide's "benefits." The specific language of H.R. 1627 is problematic for several reasons.

First, H.R. 1627 requires EPA to consider the direct *or indirect* benefits of a pesticide when the dietary risk from the pesticide is not as great as the risks to health or the environment of not using the pesticide. The legislation does not place any limit on how much dietary risk is acceptable to trade off in this situation, and further, it is not clear as to what "indirect" protection might include.

H.R. 1627 suggests that a benefit to the environment may be weighed against a health-risk to consumers. Not only is this type of comparison difficult to make especially when environmental benefits are hard to determine and quantify but it is also problematic in a food safety statute. The bills language implies that a benefit may outweigh the risks associated with *any* risky pesticide. It is not clear what criteria should be applied to the other risky pesticide.

The language of H.R. 1627 also expands current law, which requires the Administrator to consider the "necessity for the production of an adequate, wholesome, and economical food supply" and would require the Administrator to take "national and regional effects" into account. It is not clear what problem this broader language intends to resolve.

The Administration has proposed establishment of a strictly health-based standard for food safety, while providing for a transitional period during which benefits could be considered in circumstances involving significant benefits to consumers or impacts on domestic food production.

We believe that a single health-based standard for food safety is critical to guiding decision-makers, as well as providing credibility to producers and assurance to consumers, that the pesticide used in food production will protect health.

In short, the American public should have confidence in the safety of the food supply, but the kind of broad economic benefits language contained in H.R. 1627 is problematic in a food safety statute.

Special Provisions for Infants and Children

H.R. 1627 includes some provisions in response to the NAS report on *Pesticides in the Diets of Infants and Children*, and in that respect is an advance over the House bill presented in the last Congress. However, we believe that more is needed to ensure adequate protection. H.R. 1627 provides measures to ensure that needed information about children's diets and pesticide residues are available. We would like to see requirements that this information, along with information about susceptibility, be used in developing tolerances.

The Administration's proposals for tolerance setting contained additional requirements directly responsive to recommendations contained in the NAS report. EPA would be required to consider unique aspects of children's diets and potential sensitivities to pesticide risks. EPA would issue specific findings that tolerances are safe for infants and children. We want to work with Congress to enact the necessary safeguards.

Tolerance Procedures

Under current law, a tolerance may be revoked through use of a full, formal evidentiary hearing, which litigants have used successfully to delay action on pesticide tolerances.

As drafted, H.R. 1627 not only retains time-consuming hearing procedures but actually sets up inconsistent procedures, depending on whether the tolerance action is initiated by EPA or an outside party. For example, if objections are filed to a rule *establishing* new tolerances requested by a pesticide manufacturer, the tolerances go into effect and the hearing takes place afterwards. However, if EPA initiates a revocation proceeding, objections to the *revocation* entitle the objector to a hearing prior to finalization of the revocation. This kind of inconsistency is a double standard that undercuts the basic premise of a public health/food safety protection law.

The Administration's proposal contained a straightforward notice and comment procedure with judicial review for petitions or actions on EPA's own initiative to establish, modify, or revoke tolerances, which should be adequate to protect the interests of producers, growers, and consumers alike.

Consistent with the Administration's proposed FIFRA amendments, time-consuming hearing requirements would be dropped.

Finally, H.R. 1627 is silent with respect to the review of existing tolerances. The Administration, however, proposed to review existing tolerances to ensure that they meet the health-based standard. Further, the Administration also proposed that all pesticide applications be updated periodically to ensure that tolerances keep pace with advances in scientific knowledge. Without these provisions, there is no guarantee that 15 years from now, Congress and the regulatory agencies will not face a situation similar to the one we face today.

FFDCA/FIFRA "Coordination"

As drafted, the coordination provisions of H.R. 1627 could be read to have the practical effect of negating all of the safeguards, including those aimed at protecting children, in the FFDCA provisions of the bill with respect to existing tolerances. If this is not the intended result, these provisions need to be clarified.

H.R. 1627 contains provisions designed to coordinate regulatory proceedings under the FIFRA and FFDCA, with EPA being required to take action first against a pesticide's registration before finalizing a tolerance revocation. In terms of timing, this makes good sense and is the practice generally followed by EPA currently. It should be made clear, however, that any "coordination" provision for timing regulatory actions under the two statutes does not affect the substantive provisions of FFDCA.

The language in H.R. 1627 states that even if EPA has determined that a tolerance should be revoked under the FFDCA the Agency can be required to conduct cancellation proceedings before the revocation becomes final. However, the standards for registering pesticides under FIFRA can be less protective of consumers subject to dietary risks than the standard for tolerance setting under the FFDCA because FIFRA allows for a broader range of considerations. Because H.R. 1627 provides that FIFRA must be complied with first, we are concerned that if the FIFRA provisions are not the basis for proceeding against a pesticide, the Agency cannot move to revoke a tolerance or limit the pesticide's use.

The Administration's proposals also addressed the issue of FIFRA/FFDCA coordination, and achieving greater consistency in statutory standards. Our position is simple: if a tolerance is not safe, the registration must be addressed so that farmers following label instructions do not run the risk of producing adulterated food crops.

Enforcement Authorities

H.R. 1627 would allow issuance of a pesticide tolerance even if a practical analytical method for detecting and measuring the pesticide residue were "unavailable" or "not feasible." In short, the bill does not require industry to identify analytical methods for new pesticides. Thus, the bill would allow the setting of a tolerance for a pesticide that is impossible to detect. Therefore, EPA could approve a pesticide as safe, anticipating low residue levels. However, since FDA would have no way of determining whether residue levels were actually as low as expected, we would have no way of knowing whether the food supply was actually safe.

In addition, H.R. 1627 has no provisions comparable to the Administration's proposals for enhanced FDA enforcement powers with respect to violative pesticide residues in food, including the authority to require recalls, embargo violative foods, and levy civil penalties for violations. The Administration believes that the pesticide statutes need to be reformulated and that providing FDA with proper analytical methods and enforcement tools is a critical and essential part of that reform.

We believe that it makes no sense to reform the law if, because of a lack of adequate enforcement authorities, the laws cannot be properly enforced.

Uniformity/preemption of State Tolerance-setting Authority

As you know, the Administration has taken no formal position on the specific issue of pre-emption of state authority under FFDCA. H.R. 1627 extends preemption to warnings or other statements about the presence of pesticide residues in food and consequently appears intended to over-ride state laws such as California's Proposition 65 requirements.

International Standards

As a matter of policy, EPA takes the standards for pesticide residue levels set by the international Codex Alimentarius Commission into account when re-evaluating tolerances in connection with pesticide reregistration eligibility decisions. All tolerances must, however, continue to meet U.S. food safety standards established under the FFDCA. EPA also must comply with obligations regarding the use of international standards under international trade agreements (North American Free Trade Agreement and World Trade Organization's Sanitary and Phytosanitary Agreement), but these agreements clearly allow EPA to set tolerances to achieve a higher level of protection for U.S. consumers than might be afforded by use of the Codex standards.

H.R. 1627 could potentially alter existing practice, placing a burden on EPA to justify any departure from Codex levels. Perhaps unintentionally, the bill as drafted goes even further and could conceivably compel EPA to accept Codex levels that violate H.R. 1627's core safety standard, that tolerances must be "adequate to protect public health," if benefits outweigh risks.

U.S. tolerances may differ from Codex standards because of unique pest control conditions in the U.S., different dietary patterns, or because of different health and safety standards. U.S. tolerances may therefore appropriately be higher or lower than Codex standards, which do not take these factors into account. H.R. 1627, as drafted, may result in registration and tolerance changes that could inhibit effective pest control in some growing regions, and ignore U.S. dietary patterns.

Consistent with our trade agreement obligations to consider international standards in setting pesticide residue tolerances, we believe it is appropriate for tolerance petitioners to address this issue in their submissions to EPA, and to explain their reasons for requesting tolerances that may differ from Codex levels. EPA would then consider and respond to this issue when it publishes final tolerance regulations. We do not believe that new legislation is needed to accomplish this.

III. FIFRA PROVISIONS

While some of the FIFRA amendments in the current version of H.R. 1627 reflect advances over previous iterations proposed since 1989, others would encumber rather than streamline regulatory processes. Others may make achievement of public health and environmental goals more difficult, compared to current law.

Cancellation

Notably, the *cancellation* procedures in H.R. 1627 combine the time-consuming features of both rule-making and formal adjudicatory hearing procedures. While specifying strict time limitations for steps in the regulatory process, the bill's provisions simultaneously make adherence to these deadlines impossible. For example, provisions limiting hearings to 20 days are likely to prove unworkable in practice, since limiting hearing presentations or cross-examination may be grounds for overturning a cancellation rule.

We support the goal of streamlining regulatory procedures. But the bill as drafted simply does not achieve that goal, and in fact may further prolong cancellation proceedings. Both farmers and the public suffer when pesticide risk concerns remain unresolved for long periods of time.

H.R. 1627 as currently drafted does not achieve its stated streamlining objectives. A straightforward notice and comment procedure as used under other regulatory statutes, as proposed by the Administration, would be a more appropriate way to resolve the kinds of scientific issues likely to arise in a cancellation proceeding. Such a procedure would of course allow for prompt judicial review of EPA's decisions. Unless these cancellation provisions in H.R. 1627 are modified substantially, we would prefer existing law.

"Burden of Proof"

A provision contained in H.R. 1627's "conforming amendments" appears to shift the burden of proof of a pesticide's safety from the pesticide manufacturer/registrant to EPA. Long-standing regulation (adopted after notice and comment), case law and policy have placed the responsibility for showing that a pesticide meets the standards for registration on the proponent of registration. This is simply common sense. The public should not bear the risk of exposure to questionable pesticides; it is up to those who market pesticides to demonstrate that safety standards are met.

Other "conforming amendments" as well as the detailed cancellation provisions deserve careful scrutiny to ensure that existing protections are not compromised. For example, one provision could complicate and possibly attenuate the effectiveness of EPA's existing authority to require registrants to submit data about the health and environmental effects of pesticides and suspend registrations which are not supported by timely and adequate data. Any change in existing law should be supported by clear evidence that there is a problem requiring correction in the statute, and that our ability to address health and environmental concerns would not be compromised.

Minor Uses

The Administration supports inclusion of provisions to encourage the registration and maintenance of pesticides for important "minor uses," provided that certain criteria are met to ensure that these uses are in the public interest, maintain effective means of pest control and do not raise health or environmental risk concerns. If risk questions arise, EPA must be able to act quickly. H.R. 1627 meets this requirement.

Minor use pesticides whose primary function is to control public health problems (e.g. vector-borne diseases) should also be covered by minor use incentives, provided that data are sufficient. In some cases, the economic incentives for developing such data may be lacking, and it is for this reason that the Administration's proposals in the last Congress included provisions for consultation with the Department of Health and Human Services/Public Health Service and support for necessary data development. Such a program would be analogous to USDA's IR-4 program for agricultural minor uses. The Subcommittee may wish to incorporate such a program into H.R. 1627's current minor use provisions.

Fees

As pointed out in previous testimony by this Administration as well as by my predecessors in previous Administrations, EPA needs a reliable resource base in order to accomplish its statutory mandate to complete reregistration of older pesticides on an accelerated basis. H.R. 1627 contains no FIFRA fee provisions to support this work. Should authorization for existing fees be allowed to expire in 1997, the result would be disruption, significant decreases in EPA's scientific staff, delayed decision-making, and loss of confidence in the pesticide regulatory system.

As far as growers and the public are concerned, it is never a good answer for EPA to say that we have not been able to assess a pesticide's safety based on current scientific standards. When questions arise, public confidence can be maintained only if EPA can respond that it has completed its assessment and found the pesticide use to be safe.

Updating Regulatory Procedures

While H.R. 1627 addresses a number of critical issues, there are other important changes that would make our regulatory framework more responsive to scientific advances and provide the Agency with flexible tools to achieve public health and environmental goals.

Specifically, in last year's legislation we proposed that periodic reassessment of pesticide registrations against current safety standards, along with other authorities, such as the ability to implement relatively minor changes in labeling or other

conditions of registration and to maintain the availability of pesticides under controlled conditions to preserve effectiveness in IPM programs.

FIFRA's enforcement and penalty provisions are outdated and badly need upgrading to make all regulations fully enforceable and impose penalties commensurate with the nature and severity of the offense.

Finally, the Administration proposed changes to FIFRA to encourage sound pesticide product stewardship throughout the world, reduce the possibility that pesticides exported from the U.S. would return as unsafe residues on food imported into this country, and enhance the ability of pesticide-importing countries to make informed decisions on potentially hazardous pesticides that may be shipped to them. We urge Congress to seriously consider such reforms as it attempts to craft comprehensive pesticide legislation.

IV. DATA COLLECTION

While we appreciate H.R. 1627's attempt to place statutory priority on Integrated Pest Management (IPM) approaches, better pesticide use data, and improved information on actual pesticide residues in foods (especially foods consumed by infants and children), we do not believe that the current bill goes far enough in this respect. In particular, there are no provisions to encourage the development and registration of roduced-risk, safer or biological pesticides, or to provide resources for improved data collection activities. The President's budget has consistently requested the funding required to carry out the tasks mandated in HR 1627 such as IPM programs, IR-4 pesticide use surveys, and dietary intake studies. Unfortunately, Congress has not provided the necessary funds. Without appropriations commensurate to the tasks presented in this bill, very little of the legislation's intent can be accomplished.

V. CONCLUSION

It is time for the Administration and Congress to work together for common sense reform of our pesticide laws, to reach agreement on legislation that will protect public health and the environment, maintain and enhance public confidence in the safety of the food supply, and facilitate the development and adoption of safer, effective pest control technologies.

Any new pesticide legislation should establish a single, health-based standard for pesticide residues in food. It should also ensure protection of our children from pesticide risks consistent with the NAS report and provide for fees to support completion of reregistration. Together, we need to work out and resolve our differences, make changes where necessary, and focus on these common goals.

Thank you again for the opportunity to join you this morning. We look forward to working with this Subcommittee and others in Congress to enact meaningful reforms. Change is long overdue.

Mr. BILIRAKIS. Thank you, Mr. Elworth.

I'll start the questioning, and, as I've indicated at the outset, I'm going to hold strictly to the 5-minute rule in the interests of time.

Dr. Goldman, EPA does consider health effects other than cancer in making tolerance decisions right now, do they not?

Ms. GOLDMAN. Yes, we do.

Mr. BILIRAKIS. All right. I'd just like to run down the checklist of issues that the EPA considers in registering the use of a specific pesticide on a specific food to make sure we all understand what health effects the agency currently examines. Does the agency require the submission of data concerning a pesticide's acute oral, dermal and inhalation effects, reproductive system effects, chronic effects from dietary exposure, oncogenicity effects, mutagenesis effects, fetal effects, delayed neurological effects, plant and animal metabolism effects?

Ms. GOLDMAN. All those are required to register a pesticide unless a pesticide fits in certain categories. We have some pesticides for which we do not require all those data that we have issued PR notices on, but for the ones that we think are likely to be toxic, yes, we require all those data.

Mr. BILIRAKIS. All right. Given the wide range of health effects that the agency currently considers, I'm not sure that I understand EPA's concern that the negligible risk standard in this bill, H.R. 1627, is unclear with respect to noncancer risks. Are you saying that under the language of H.R. 1627, the agency would somehow no longer be able to consider all the factors we just went through or would not be able to consider new factors?

Ms. GOLDMAN. Let me sum up what the concern is. The term "negligible risk" was developed in order to deal with a problem that we have when we regulate carcinogens where we assume there is not a threshold, we assume that there is no level at which there is no effect. In toxicology for most health effects we have something that we call a no observed adverse effect level. That is a level below which nothing happens to the animals who are tested. Above that level there are adverse effects.

For some—it used to be all, but now it is still most—carcinogens, we assume there is no such thing as a threshold, and therefore we can't guarantee a no effect level. Instead, what we go for is a negligible risk which is that the risk is so small that in essence it is negligible, but theoretically there is still some risk there.

The standard that we proposed last year of a reasonable certainty of no harm means for the noncancer risks that we are below that threshold of effect, and for cancer we have a negligible risk. That has a clear legal interpretation, and we just don't understand what the legal interpretation of negligible risk would be for those noncancer effects, those effects for which there is a threshold.

Mr. BILIRAKIS. As I understand it, you get to set that, don't you? Isn't that part of your responsibility?

Ms. GOLDMAN. Well, I think that part of what we need to engage in as a part of working out this legislation is a dialog, because what will happen is that in court, if this legislation were enacted, they would want to know what was the legal intent of Congress, what does Congress intend.

I think part of why we are raising the issue and we want to discuss this issue of the standard with you is to understand what the intent of Congress would be in establishing a standard of a negligible risk for a noncarcinogen.

Mr. BILIRAKIS. I would hope that in the interests of protecting the public health which we are all interested in—both Republicans and Democrats—that that is something that can be worked out. But, again, it seems that the responsibility basically is yours and we shouldn't be getting away from that.

I'm concerned—and Mr. Bilbray, among others, accented this—that the administration doesn't seem to want the appropriate flexibility, for the agency to take advantage of the best science, which is the goal of H.R. 1627.

The administrator testified before this subcommittee previously—and I quote, "that in order to ensure that future EPA decisions and risk assessments will reflect the best of evolving science, the statute itself should not prescribe in detail the risk assessment assumptions and methodology that the agency should use in evaluating whether a pesticide meets the safety standard." The question is, how does H.R. 1627 not reflect this philosophy? I think it is intended to, and isn't EPA better qualified to make scientific deter-

minations than the Congress? So if we get too definitive we certainly are making those scientific determinations in this ivory tower here. I would ask you in the interests of time to withhold the answer to this question, but possibly before we finish up you might get to it.

Ms. GOLDMAN. I can actually do it very briefly.

Mr. BILIRAKIS. All right.

Ms. GOLDMAN. We do appreciate that H.R. 1627 does not prescribe in detail how we should do the risk assessment procedures, and we are in agreement with the chairman that legislation should not do that so that our hands are not tied in the future when the science changes.

Mr. BILIRAKIS. All right. Thank you.

Mr. Waxman.

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

I think we ought to be concerned about basing our decisions on sound science, and what worries me about this legislation, which I think is quite extreme, is, it is not based on sound science.

We asked the National Academy of Sciences, the premier scientific institution in this country, to look at the problems of pesticides in children, and they have given us recommendations, and it is my contention that those recommendations are absolutely ignored in this legislation.

Mr. Schultz, I would like to ask you this question about H.R. 1627 and its relationship to the NAS report on pesticides in the diets of infants and children. On page 1 of the NAS report it says "tolerances constitute the single most important mechanism by which EPA limits levels of pesticide residues in food. Unfortunately, under this bill tolerances would no longer appear to be the most important mechanism for protecting the food supply. Instead, we would have a far weaker standard of FIFRA which would appear to take precedence." And I would like to direct your attention to the harmonization, so called, provision on page 80 of the bill which says that the administration must act first under FIFRA, not the tolerance provisions of the Federal Food, Drug, and Cosmetic Act. Are these provisions consistent with the Academy recommendation that tolerances serve as the most important mechanism for limiting pesticides in food?

Mr. SCHULTZ. Mr. Waxman, we don't believe they are, and we don't believe they are consistent with the current law either. The bill seems to say that before you could take a pesticide off the market you would have to go through the entire FIFRA process and find that it doesn't meet the weaker FIFRA standards, so it seems to do exactly the opposite.

Mr. WAXMAN. On pages 8 and 9 of the academy report it says "Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins." Do you think H.R. 1627 achieves this goal?

Mr. SCHULTZ. It mentions children, but it doesn't seem to require EPA to do anything specific, make specific findings or do the kinds of things that the report envisioned.

Mr. WAXMAN. Dr. Goldman, do you agree with Mr. Schultz on this fundamental point?

Ms. GOLDMAN. Yes, we think that it could be strengthened in that regard, and, as I said before, we are also concerned not only about the coordination but also about the very broad benefits language which doesn't set a specific limit on the kinds of benefits that would be considered in allowing more than a negligible risk.

Mr. WAXMAN. The NAS also made a number of specific recommendations, one of which was on page 11 of the report, and it says, "All exposures to pesticides, dietary and nondietary, need to be considered when evaluating the potential risks to infants and children." Mr. Schultz, does H.R. 1627 require EPA to consider all exposures to pesticides as NAS recommended?

Mr. SCHULTZ. It doesn't appear to require that or anything very specific.

Mr. WAXMAN. On page 11 the NAS also recommends that EPA consider synergistic effects of pesticides with common toxic effects. Dr. Goldman, does H.R. 1627 require you at EPA to consider these effects?

Ms. GOLDMAN. There is no specific requirement in that regard.

Mr. WAXMAN. Dr. Goldman, H.R. 1627 treats the inert ingredients that make up over 90 percent of most pesticides. As I understand it, these inert ingredients are regulated but they could be essentially deregulated under H.R. 1627. Could you comment on this?

Ms. GOLDMAN. We think that it is very important that we assess the inerts as well as the active ingredients in pesticides. Some of the inert ingredients, although they may not be active against the pest that is being controlled, may have activity in terms of biological activity for humans.

Mr. WAXMAN. Why is that?

Ms. GOLDMAN. Basically, the definition of inert just identifies whether it is targeted against either the insect or the weed or the other pests that the pesticide is trying to control. The definition of an inert has nothing to do with the toxicology for humans, and we do need to look at toxicology for humans for any product that is going to be on food.

Mr. WAXMAN. Are we talking about product ingredients like benzene or formaldehyde that might be an inert ingredient?

Ms. GOLDMAN. In the past there have been ingredients like that, and there are still inert ingredients that we need to look at today.

Mr. WAXMAN. And would H.R. 1627 let these dangerous chemicals back into pesticides as so-called inert ingredients?

Ms. GOLDMAN. We think that H.R. 1627 would tend to relax the standards and make it more difficult for us to control the levels of the inert ingredients.

Mr. WAXMAN. Mr. Chairman, let's adopt legislation based on sound science and take to heart the recommendations of NAS.

I yield back my time.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Bliley.

Mr. BLILEY. Thank you.

Ms. Goldman, I'm confused by EPA characterization of the risk standard in H.R. 1627. The bill establishes a single negligible risk standard for tolerances for pesticide residues in both agricultural commodities and processed foods. It states that a tolerance may not be established that is at a higher level than one which the adminis-

trator determines is adequate to protect the public health. The bill further states that the phrase "adequate to protect the public health" means that the risk cannot be more than negligible. The bill further requires the EPA administrator to set forth by regulation the factors and methods used to determine negligible risk.

The administration's testimony expresses concerns that the bill is not specific in defining negligible risk, yet EPA had in place a negligible risk policy defined as one in a million risk that it went to great lengths to defend in court. Indeed, the current EPA administrator testified before this subcommittee last Congress and stated that in terms of carcinogens the administration's recommended standard, reasonable certainty of no harm, meant that the dietary risk is negligible. Further, the administrator stated that the agency would implement this negligible risk standard with a risk calculation of one in a million. What would prevent the agency from implementing the negligible risk standard for carcinogens as a risk calculation of one in a million?

Ms. GOLDMAN. I think that in terms of the way the statute has been drafted, clearly for a carcinogen we would probably do the same thing that we do today, and that is, today we would use the models that we use and probably interpret the risk that we are targeting as somewhere around one in a million. But the problem is that the issue is for noncancer risks where we don't use those kinds of models and extrapolations. Instead, for those risks there is actually a threshold, there is actually a dose below which you don't have an effect, and that is where I think we need to have a dialog with the authors to understand how we would interpret the term "negligible risk" as a standard when it is not a carcinogen.

Clearly if it is a carcinogen would do as we do today, and, as we argued in court, we should do, but the real question is for noncancer risks, for neurotoxicity, birth defects, miscarriages, how we would interpret a negligible risk standard.

Mr. BLILEY. In terms of benefits, Ms. Goldman, does EPA make the assumption that any loss of production in the U.S. can be made up by imports from other countries?

Ms. GOLDMAN. No, we do not. When we do our FIFRA registration activities we do not look at that issue of imports. Under FIFRA, which, as you know, is a risk-benefit balancing law, we look at the availability of alternatives for the farmers and what we think they are going to be—what we project to be the costs of the decision as opposed to the benefits of the decision.

Now in terms of FFDCA today in terms of setting tolerances, we do not use benefits considerations. We tend to set tolerances based on health concerns alone, and we think that that is generally an appropriate way to do this.

It has been pointed out to us that there may be times that there are health considerations theoretically—that there are direct health benefits to consumers from the use of a pesticide on food, and we think that that is a benefit to the consumer that we ought to be willing to think about. But in terms of other kinds of benefits, I think we have to be very careful about weighing benefits to one group of people in exchange for risks to another group, and that is why, when we see the very broad language in H.R. 1627, we are

quite concerned because it would be a departure from current practice.

Mr. BLILEY. Thank you.

Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Towns.

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

Dr. Goldman, do you believe that this bill gives you sufficient flexibility to develop standards that will respond to the special needs of children and infants?

Ms. GOLDMAN. I think that in terms of actually using data on kids' risks that we would be able to do that. I think the greatest concern about children is in two areas: One, how the negligible risk standard would be interpreted, say, in a court of law, and I think that is something we are going to work out with the committee; I feel confident that we can work out what the standard should be. And, two, how the benefits language would be construed in terms of allowing economic benefits to outweigh protections for children, and that is an area about which we have a lot of concern and that we want to work with Congress on.

Mr. TOWNS. Thank you.

Would you agree that once a Federal standard is established by EPA that we should not have States coming in with warning signs and requirements of other measures that prohibit the sale of food that EPA has established as safe through a national science-based standard?

Ms. GOLDMAN. We believe that there is a balancing here that needs to be done, that States have the obligation and the right to protect their own citizens, but that we also need to have a national food safety program that protects all Americans.

I'm aware that there are issues that are raised by H.R. 1627 in terms of the ability of States to set tolerances, and we have been having discussions with some of the States about this. Some of them feel that if they don't have that ability, that that removes from them some of their ability to either protect people in their own States or to even leverage the Federal Government to set tolerances when they feel that the Federal tolerances are not stringent enough. I think this is something that we need to work out with the States so that we end up with the appropriate balance of responsibility between the Federal and State government in this area.

Mr. TOWNS. I think about the production and marketing, and also I think about the fact that there is a history of some States sort of being selfish for reasons other than health or safety. What are your views on that? I mean I'm sure you have experienced it somewhere along the line.

Ms. GOLDMAN. Well, the reality today is that although States are allowed to set tolerances if they want to, we don't have any situation where there are separate tolerances for States, and so although I think it could be complicated if the States were going off creating their own standards, they haven't actually been doing that so we haven't seen misbehavior by the States, if you want to put it that way, in this area at all. In fact, we have found that the States are extremely reluctant to set their own tolerances.

Mr. TOWNS. The point I'm making is that I've seen it in other areas and I think that we have to be concerned and sensitive to the fact that it could happen in this particular area as well, and I think that is something that you, I'm certain, would be very sensitive to as well.

Ms. GOLDMAN. Yes. I would just say that the right way to work this out would be to include the States in developing a solution that properly recognizes their authorities and their jurisdictions in terms of protecting their citizenry.

Mr. TOWNS. Right.

Even though our committee lacks jurisdiction over these provisions of the bill, if we did not enact pesticide reform this year what economic impact do you believe recent court decisions will have on agriculture, particularly, I guess, in the minor crops?

Ms. GOLDMAN. The impact is going to be on the use of approximately 35 pesticides, and it is approximately 80 pesticide food combinations that currently have tolerances which, as a result of the court ruling, will possibly not exist in the future. What we are doing is—you know, the court ruling from 2 years ago is systematically reviewing these, making sure that they are covered under Delaney and making sure that indeed we do need to revoke them, and then we have promised the court that we will in a very systematic way carry out those actions. This will have an economic impact on certain crops, certainly on certain pesticide producers as well.

What we are trying to do to mitigate that is to do this in as predictable a way as possible. We have signaled every step of the way what we are going to do and when we are going to do it to allow people to make any adjustments that need to be made.

Mr. TOWNS. Mr. Chairman, I see my time has expired, and I yield back.

I think that what I gather from your statement is you are saying that this wagon is broken and it needs to be fixed.

Ms. GOLDMAN. We said that last year with the reform bill that we sent forward. We feel that there needs to be fundamental reform in the food safety laws, both the food law and FIFRA.

Mr. TOWNS. Thank you.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Whitfield.

Mr. WHITFIELD. Thank you, Mr. Chairman.

Ms. Goldman, I wanted to ask you a question relating to your 1992 U.S. Court of Appeals decision out in California which ruled illegal the de minimis rule relating to section 409, but it didn't say anything about section 408 on the raw commodities side. Is that because the Delaney Clause is not there on that. Why, then did the EPA enter into a consent degree voluntarily to expend scarce funds and resources defending the revocation of these 80 or so pesticides that you are going to require not to be used any more? Why did you all enter into a consent decree on that when you probably could have done it in another way?

Ms. GOLDMAN. I think your question really has two parts, and I'll start out with the part of why did we enter into in a consent decree. We did not want to end up in a situation, as the agency often has, where the court is managing our administrative processes, and we felt that a consent decree would be far preferable to

losing and then ending up having a process micromanaged by the court—what has happened to the EPA in many, many instances in the past, as I'm sure you are well aware.

In terms of the issue of 409's, the tolerances on processed foods, versus the 408's, which are the tolerances on fresh fruits and vegetables, what we agreed to do was to, by some date certain, articulate our policy on those, on coordination of those, and then act appropriately after we did that.

The issue—and it is really an issue between EPA and FDA and USDA is that the legal use of a pesticide should result in legal food, and many have contended that foods could be segregated, that there could be treatment of foods and some of those fresh fruits and vegetables can go into the fresh fruit and vegetable market, others go into the processing market, and thus not have a problem with the 408's as a result of Delaney, but that has consequences for the farmers in terms of the actual ability to guarantee that. It also has consequences for the FDA in terms of being able to enforce that.

So that is an issue that we have to work on across the Government in terms of deciding what our policy is and how we will handle that question. But it is a very serious question, because it would not be right for the farmers if they follow the rules and use pesticides as legally allowed and then have the food that is produced end up being illegal food. That would not be right for the farmers.

Mr. WHITFIELD. But you are actually going to eliminate the use of about 80 pesticides which your agency has basically said are safe, and have been used in the past. Now you all are voluntarily agreeing to a consent decree that is going to require that these not be used.

Ms. GOLDMAN. We are not eliminating 80 pesticides from the market. They are 80 individual uses, use of an individual pesticide on an individual commodity that are at issue, and we have not made final decisions on these as well. What we have pledged to do is to make the decisions, and, in addition to that, we have pledged to look at other data that we have where we haven't necessarily made a determination that a 409 would be needed and examine those as well.

Mr. WHITFIELD. Back in 1992 I know some of the food industry groups filed a petition urging EPA to rescind its coordination and concentration policies. That has been pending now for about 3 years, and yet you all have not taken any action. Why would it be taking so long to address that issue?

Ms. GOLDMAN. We felt as an administration that our first priority was one of putting together reform legislation and actually trying to change the law.

What the court told us is that we couldn't change the law by taking administrative action, that the only way that the law could be changed is if Congress changed the law, and so we felt that our highest priority would be to put together some reform legislation that would change the law and that would then obviate the need for responding to that petition. Because we were not successful last year in doing so, we are proceeding with the response to the petition, and we did promise the court that we would issue a response

on a schedule along with the schedule for doing revocations. Frankly, we are still hopeful that we will see reform legislation.

Mr. BILIRAKIS. The gentleman's time has expired.

I thank the gentleman.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. Schultz, I want to ask about the role overall of FDA in pesticide regulation. Run through this very, very complicated issue, if you would, and it was touched on a little bit by Mr. Towns' question on the economic impact—but run through, if you would, more precisely what Delaney means, the impact of Delaney as it stands now, and what H.R. 1627 does in replacing Delaney and sort of delineate that if you would.

Mr. SCHULTZ. Okay, and let me make clear, I think we are just talking about pesticides.

Mr. BROWN. Yes.

Mr. SCHULTZ. The Delaney Clause applies to food additives in color additives and animal drugs, and there's a lot of confusion about that.

But as to pesticides, the Delaney Clause in the food additive provision that we are talking about, in the way the law works, there is a separate section for pesticides, Section 408. When pesticides are on a fresh crop or raw crop the Delaney Clause does not apply. When the apple is made into apple sauce, so now it is in processed food, and when the pesticide actually concentrates so it is at a higher level, there is more pesticide per product than in the apple. At this time the pesticide all of a sudden becomes a food additive, and now it is regulated under 409, and now EPA has to set a separate tolerance. When it is a food additive the Delaney Clause applies.

You are looking at me like a lot of people at this point as if to say, "why do we have all these inconsistent standards?" I think one thing that this bill does that makes a whole lot of sense is, whatever the standard is—we can argue about that—it ought to be the same in the apple sauce as in the apple.

Mr. BROWN. And that is what the Academy of Sciences suggested in the report correct?

Mr. SCHULTZ. Yes, and they said that the tolerance system, the health-based standard ought to be the one that drives food safety.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Bilbray.

Mr. BILBRAY. No questions, Mr. Chairman.

Mr. BILIRAKIS. Mrs. Lincoln.

Mrs. LINCOLN. Thank you, Mr. Chairman, and thanks for holding the hearing.

I would like to ask unanimous consent to have an opening statement in the record.

Mr. BILIRAKIS. Without objection.

Mrs. LINCOLN. Thank you, sir.

Dr. Goldman, in regard to, I guess, Mr. Waxman's questions earlier in terms of what you are required to do and your answers there, is there anything here that precludes you from doing that?

Ms. GOLDMAN. No. The only worrisome language in terms of precluding us from using any health-based data for a standard is the benefits language in the bill, and that is an area where I think we need to have much more discussion with Congress, because as written it is very broadly construed.

Mrs. LINCOLN. Yes. In the Section 301 under Title III it seems to me that you are required or certainly that there is nothing there that precludes you from being involved and certainly doing the testing and the research or looking into the issues of what Mr. Waxman brought up.

Ms. GOLDMAN. Right. The issue is whether other considerations would supersede considerations such as protecting children and other health issues.

Mrs. LINCOLN. But again, you would be in charge of that, as Mr. Bilirakis pointed out.

Ms. GOLDMAN. You have to keep in mind that when you are administering these statutes that one of the very important considerations is, what was the intent of Congress when the bill was written, and if we have challenges to our decisions it is very helpful to point to either very clear statutory language about intent or to have other discussions that are on record that support our interpretations of the statute. That is why we want to be very careful in discussing these issues with Congress to make sure that we all have a complete understanding and that it is not simply up to the discretion of the agency later on.

Mrs. LINCOLN. You have stated in the testimony in the past and certainly in correspondence with me in regard to the Delaney Clause that it should be modernized and streamlined—you have expressed that here today—to reflect a single and uniform public health standard. Clearly that is the objective of all of us here, to get broad-based policy goals there. I guess the problem really lies in the definition as a single uniform public health standard and prior to the *Les* v. *Reilly*, which I guess was the years 1988 until 1992—is that correct?—you defined negligible risk, correct?

Ms. GOLDMAN. For a carcinogen we have a clear definition of what we mean by a negligible risk, and we think we would know what to do. It is for the case of noncarcinogen risks such as birth defects, spontaneous abortions, neurotoxicity, that we are not clear what that means, and that is where——

Mrs. LINCOLN. In reference to what Mr. Bliley was mentioning, the chairman was bringing out that you have clearly defined or you have done that in previous years—correct?—in terms of negligible risk for carcinogens.

Ms. GOLDMAN. For a carcinogen, yes, I think we have complete clarity about what that means.

Mrs. LINCOLN. So you don't have any problem with that, it would be certainly with the noncarcinogen.

Ms. GOLDMAN. Right, and that is why last year we proposed a standard. What we said was a standard of a reasonable certainty of no harm, which for a carcinogen would mean a negligible risk standard, and we felt that that broader language would cover us for all public health concerns.

Mrs. LINCOLN. So you just want to put a "one size fits all" as opposed to really dealing with the differences?

Ms. GOLDMAN. We either need language that is broad enough that it matches with everybody's current understanding of what we mean or we need to have it on the record or in the bill that what is meant by negligible risk for a noncarcinogen is in essence what we would do in current practice to protect public health. We are not looking for changing current practice, we just want to make sure that the standard wouldn't be interpreted the wrong way.

Mrs. LINCOLN. Prior to 1992 though you did develop the definition in terms of negligible risk for a carcinogen?

Ms. GOLDMAN. For a carcinogen, yes, and so has FDA. I think there is a lot of history here in terms of case law and administrative practice that tells us what to do with the concept of negligible risk for a carcinogen.

Mrs. LINCOLN. But there is nothing—going back to Mr. Waxman's questions, there is nothing that precludes you from dealing with those noncarcinogens in terms of——

Ms. GOLDMAN. It wouldn't preclude us, except I think if it is not clear what Congress's intent is in this matter, that our decisions could be subject to challenge and that that could be very troublesome. If you trace back the history of the term "negligible," what it really means is that theoretically there are a few cases that might occur, and we certainly don't want to allow a few birth defects or miscarriages or neurotoxicity cases from legal use of a pesticide on food because there is a threshold for those effects. We can do much better than that.

Mrs. LINCOLN. I was particularly pleased to see in this legislation we are reviewing today the inclusion of data collection regarding the diets of infants and children. I know that last year's bill did not have that in it, and I had certainly considered it a weakness, and that you have indicated some concerns with this provision——

Mr. BILIRAKIS. The gentlelady's time has expired.

Ms. GOLDMAN. I should just say we are very supportive of the provision, and we would just want to go a little further and not only collect the data but have a requirement that we use it. Certainly if we have the data we will use it.

Mr. BILIRAKIS. Thank you.

Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman.

Dr. Goldman, let me just read a couple of quotes to you from Administrator Browner. This was in the New York Times, 2 February 1993. "We have gotten to the point where we have to say we know a lot more about these chemicals than we did 35 years ago when the delay Delaney Clause was passed." And in February 1993 also in Time magazine, "There are scientific anachronisms that get created any time you have a 30-plus-year-old environmental regulation. It is time to revisit Delaney with the knowledge we have now".

Now if I understand your testimony, you want to see revisions to Delaney but you don't like H.R. 1627. Is that accurate?

Ms. GOLDMAN. What we are trying to do is to point to areas in H.R. 1627 where we think we need to work with Congress on areas that we think are not clear or to identify areas that would make the law worse than existing law as is the case of some of the FIFRA provisions.

Mr. BURR. What will happen under existing law if there is no change?

Ms. GOLDMAN. Under existing law if there is no change, one, we will have to continue carrying out the Delaney Clause, and I should point out it has now been 37 years since Delaney has been enacted and we have never had an administration that has taken the Delaney Clause literally for pesticides. Thirty-seven years—if you think about that, how many laws there are in that kind of state?

Two, we will continue to have a situation where there are three standards for pesticides on foods, which we think is a confusing situation.

Three, we will continue to have FIFRA provisions that are cumbersome and need to be streamlined.

We would like to see a reform bill that would address all of these concerns. We feel that this particular bill would not streamline FIFRA, it would actually make FIFRA even more complicated and cumbersome. We cannot support that. We—as well as other past administrations—have come here to Congress to try to improve FIFRA. We remain committed to that.

Finally, the bill does not address the need for renewing reregistration fees and bringing up to date the out-of-date pesticides that remain on the market as one of the most important things that we are doing. We have dealt with 100 out of the 400 that need to be brought up to date. That is still 300 more. We have not completed that job.

Mr. BURR. Based upon the court decisions, is there an economic impact that will hit the American consumer and manufacturing base if Delaney is not changed?

Ms. GOLDMAN. We have looked at economic impacts, and we do not project impacts to the consumer, but we do project impacts both to some segments of the agricultural community and to some segments of the pesticide production industry.

Mr. BURR. Well, certainly if there is a cost in the chain I think the consumer will bear some of that.

I was interested because you stated in our opening remarks that economic consideration is not appropriate in H.R. 1627. Let me read you one other quote from a paper, "The Delaney Clause is an outdated approach for protecting consumers from pesticide residues. Clearly the loss of selected pesticide uses may affect the price or seasonal availability of particular commodities. Theoretically, a zero risk approach to cancer for these pesticides could lead to use of alternative pesticides with more net risk but no cancer risk. These costs to society buy little in the way of additional public health protection." Lynn Goldman, EPA November 25, 1994, Science magazine.

Ms. GOLDMAN. I was going to say, I could have written that, but I guess I did.

Mr. BURR. You did.

So I would ask you, apparently there is an economic consideration that we all must make, because I think that your statement there alluded to the fact that there was an impact.

Ms. GOLDMAN. Right, and I think that we have supported modernizing the food safety standard, but we would not support the kind of broad benefits language that we see in the current version

of H.R. 1627. When I say that the Delaney approach doesn't make sense is not the same as saying that we would therefore support this other approach.

Mr. BURR. Okay. Let me say that there was also an Executive Order 12866 which directs Federal agencies to consider costs and benefits of available regulatory alternatives.

Mr. BILIRAKIS. The gentleman's time has expired, if you could finish it up.

Mr. BURR. If I could wrap it up, how does this affect this Executive Order? Is there an issue there that says we have to look at the cost versus the benefit?

Ms. GOLDMAN. Yes, and we do follow the Executive Order very faithfully, and when we do major actions with pesticides we do regulatory impact analysis where we look at the costs and benefits, and I will say as a decisionmaker that I find that to be helpful in making decisions.

Mr. BURR. Very good.

Mr. Chairman, I'll just end with a quote in the Detroit News. "If the Delaney Clause were applied to nature, we'd all starve." Thank you. I yield back.

Mr. BILIRAKIS. I thank the gentleman.

Dr. Coburn.

Mr. COBURN. Thank you.

I'm somewhat confused, and see if you can straighten me out. Is there any language in this bill that precludes you from following NAS guidelines and recommendations?

Ms. GOLDMAN. None of the language in the bill would prevent me from using data about kids' diets and risks when I make a regulatory decision. But some of the language could be construed as possibly, one, changing the standard that we use today for noncancer risks and, two, allowing other considerations to override the health risks.

Mr. COBURN. Tell me where the language is that will change that standard.

Ms. GOLDMAN. Well, I think we have had a lot of dialog here today about our concern over the need to clarify what the term "negligible risk" would mean for a noncarcinogen, and so I don't think I need to go into that any more in detail.

Mr. COBURN. No, I think you do. I think we need to clarify it, because what we have done is jumped all around that word and haven't talked about it. I understand what "negligible risk" means, and I understand what that means as a carcinogen, as a doctor and as a physician and as a scientist. I don't have any trouble with you applying that same language in terms of neurotoxicity or mutagenesis or teratogenesis. So why is it that you all don't want to use that language? Make we can change it to where we can make it where it is something that you can use.

Ms. GOLDMAN. Yes. Let me talk you through it. I think the major issue for me, as a fellow physician, is, we do our work within a very adversarial system, and we need to have language about the standard that is understandable not only for us but also for the attorneys, regulated community, the consumer groups, all of those who might be involved in the process, certainly all of those who might want to challenge any decisions that we might make. So what we

are looking for is either clarification from Congress about what exactly would be meant by this language or a willingness to consider language that has already gone through a considerable amount of that kind of judicial and legal review so that it is clear to all the parties what it means.

Mr. COBURN. And you do have a recommendation as to that language?

Ms. GOLDMAN. Right, we do.

Mr. COBURN. And our committee staff has seen that recommendation?

Ms. GOLDMAN. Yes, I think we have had an opportunity in the last few days to interact with the committee staff on that.

Mr. COBURN. But getting back to Mr. Waxman's point in terms of following the NAS guidelines, there is nothing in this bill that will preclude you from following those guidelines or recommendations.

Ms. GOLDMAN. There are two other areas that I should mention, and one is the language on coordination between FFDCA and FIFRA which, again, may be an area where we simply need clarification on intent. But it could be read, it could be interpreted, as meaning that the FIFRA standards would override FFDCA standards, and, again, because of the adversarial nature of the system, we want to be very careful to understand what is meant there and to clarify it one way or the other. And of course, as I mentioned before, to understand the benefits language and what is meant by that language and what it would override.

For example, there is a mention about environmental benefits being weighed with the health benefits, and, frankly, I don't know how to weigh off numbers of birds killed with babies with neurotoxicity, and so we are concerned about very broad benefits language like the language that is in the bill.

Mr. COBURN. So you would like to see that language tightened up.

Ms. GOLDMAN. We would like to see that tightened up. We think we are going to need to work with you on that.

Mr. COBURN. One other area. Tell me specifically what part of the bill—where is FIFRA made more complicated by this bill?

Ms. GOLDMAN. Yes, let me explain that. Today in current practice the way FIFRA is written, when we do a cancellation and a suspension of a pesticide, there is allowed a process that is called an administrative hearing, and a lot of people involved in the system, not just the agency but many attorneys, have looked at this and felt that this is a very burdensome procedure. Recommendations have been made that that administrative hearing be replaced with notice and comment rulemaking—that is what we proposed last year. What H.R. 1627 does is, it actually does have a provision for notice and comment rulemaking, but it keeps the hearing process as well. That actually then complicates the process by having not just one but two, and, frankly, that is worse than current law.

On top of that, the standard for the hearing has changed. Today the burden is on the maker of the product to prove to the public that the product is safe. There is reference to coordination with another statute, the Administrative Procedures Act, which we think would shift the burden of the proof on to the Government to prove

that the product is not safe. This is done at the very end of the FIFRA part of the Act.

It also shifts the burden of the proof not just for hearings, for instance, for suspension and cancellation, but also for what we call a data call-in, which is one of the more important authorities which we have under FIFRA. When we have a concern about risk, something crops up that we didn't predict when we registered the pesticide, we can call in new data, but this language would bring the data call-in procedure also into conformity with APA standards, which would put more of a burden of proof on us. We don't really think this would benefit the growers because we don't think it is a good thing when uncertainties about pesticides are prolonged.

Mr. BILIRAKIS. The gentleman's time has expired.

I'm going to yield to Mr. Pallone for a couple of minutes. Dr. Goldman, the staff are available to sit down with you and try to work out some of these areas, which are probably technical areas, significant areas no less, but something can be worked out.

Ms. GOLDMAN. We appreciate that, Mr. Bilirakis.

Mr. BILIRAKIS. Mr. Pallone.

Mr. PALLONE. Thank you, Mr. Chairman.

I just arrived so I was going to ask to yield my time to Congressman Waxman.

Mr. WAXMAN. I thank you for yielding.

There are some things that we want to see if we can have a clear statement in this bill to become law and that we all know we are talking about the same thing, and I appreciate the chairman indicating that the majority on this committee is willing to work with you and the administration to clarify these points, and I think they are important to clarify because you are right, in a lawsuit you may not be able to do what you think is appropriate to do.

But there is another point too. I think EPA and FDA and Department of Agriculture ought to be told they must do certain things to protect the public, because otherwise the bureaucrats—to use a phrase that seems to be in favor at the moment when we talk about anybody in government service—will be under an enormous amount of pressure from industry groups not to do the things that will protect the broader public health.

Dr. Goldman or Mr. Schultz, this issue of whether FIFRA has to apply before any kind of tolerance would be applicable is not a minor technical point, is it?

Ms. GOLDMAN. No. We do think that the coordination issue and how that might be construed is very important. That is why we included that in the testimony. The standard under FIFRA is different than the standard under FFDCA, and we would not want to see FIFRA override our responsibility for protecting food safety.

Mr. WAXMAN. Would it be fair to say that if FIFRA did override the standard, that there is really no health standard at all?

Ms. GOLDMAN. Well, what it would mean is, it would be a very radical departure from current law and really the laws that we have had in place for a number of decades now to ensure food safety.

Mr. COBURN. Would the gentleman yield on just that one question for a second?

Mr. WAXMAN. Let me just get a clarification from the witnesses and then I will.

Mr. SCHULTZ. I just want to add to that, you can have the best safety standard in the world, but if then when you allow the benefits to override that, you have lost everything you gained. So you may have the best standards for children in the world, but if that risk is overridden by the benefit then you don't have anything.

Mr. WAXMAN. I can't imagine a parent in this country accepting the idea that if there is a risk to their child's health from a pesticide residue in food, that that will be ignored because of the economic benefits to the agriculture and chemical industries, but isn't that what we are talking about, Mr. Schultz?

Mr. SCHULTZ. That is the issue we are raising, yes.

Mr. WAXMAN. We are not going to let a tolerance be set to protect the public because that tolerance will be weakened because of these other benefits being balanced in.

Yes.

Mr. COBURN. I just wanted to get a yes or no answer to your question to the doctor in terms of—that that is no standard at all if FIFRA is overridden. I don't think that is quite accurate.

Mr. WAXMAN. No health standard—no health-based standard is really going to be applicable.

Ms. GOLDMAN. Well, FIFRA is a risk-benefit balancing statute, and so there are health considerations that are strong considerations, but it is very clear that we have to balance those health considerations with economic considerations. FFDCA does not work quite that way. There are considerations in terms of affordable, abundant food supply.

Mr. COBURN. I understand how that works. I'm just saying in terms of the response to Mr. Waxman's question, it is not truly a, yes, there is no health standard at all, because the health standard is considered in making that decision.

Mr. WAXMAN. Again, to reclaim my time, it is considered and then can be pushed aside while we look at this balancing out of the economic interest.

What we are going to propose today in legislation is to say if we are going to have this bill, let's at least have a statement in there that if a pesticide is reasonably anticipated to harm children, then the tolerance cannot be issued to allow that pesticide to be used. That just seems to me to be a common sense thing that every American parent would think makes sense not to let their children be at risk for a neurological problem or birth defects or cancer or anything else if their kids are at risk. I don't think we ought to balance it out and say, well, all things considered, we'll sacrifice some kids in order to make sure that the economic benefits still flow.

Ms. GOLDMAN. Yes, I should respond, I think, that we would agree that protecting children is of paramount importance. We also think that the standards should protect adults as well.

The other thing that I would like to respond to——

Mr. WAXMAN. Is that contradictory?

Ms. GOLDMAN. That is not in contradiction at all.

Mr. BILIRAKIS. Very quickly, Doctor. The time has expired.

Ms. GOLDMAN. Yes. In terms of Congressman Coburn's comment, I think that, again, we have to look at the very adversarial nature

of the process that we are involved in and the opportunities that this kind of linkage with FIFRA might give to attorneys who will seek to overturn decisions, and not that we wouldn't try to do the right thing, but we just want to make sure that we would be able to uphold those decisions.

Mr. BILIRAKIS. The gentleman's time has expired.

This panel is excused.

Doctor, I certainly appreciate your taking time to be here along with Mr. Schultz and Mr. Elworth. We thank you, and we have learned a lot.

Would the second panel please come forward, Dr. Carl Winter, director of the FoodSafe Program with the University of California in Davis, California; Mr. Leonard Gianessi is senior research associate with the National Center for Food and Agriculture Policy here in Washington; Dr. George Gray is deputy director of the Center for Risk Analyses, Harvard School of Public Health. They are the panelists for panel two.

Gentlemen, your entire written statement will be made a part of the record. I will ask that your oral statement be limited to 5 minutes if at all possible.

We will start with you, Dr. Winter.

STATEMENTS OF CARL K. WINTER, DIRECTOR, FOODSAFE PROGRAM, UNIVERSITY OF CALIFORNIA; LEONARD P. GIANESSI, SENIOR RESEARCH ASSOCIATE, NATIONAL CENTER FOR FOOD AND AGRICULTURAL POLICY; AND GEORGE M. GRAY, HARVARD CENTER FOR RISK ANALYSIS, HARVARD SCHOOL OF PUBLIC HEALTH

Mr. WINTER. Good morning, Mr. Chairman and members of the subcommittee. I'm Dr. Carl Winter, and I'm a food toxicologist on the faculty of the Department of Food Science and Technology at the University of California at Davis. I'm also the director of the University's FoodSafe Program which was established in 1992 to facilitate the development and sharing of research-based food safety information. The program receives no funding from the agricultural, chemical, or food industries. The views expressed today are my own and do not represent an official position of the University of California.

I'm pleased to see that the committee is seriously considering H.R. 1627 as a replacement for the Delaney Clause.

Back in the 16th century the Swiss physician, Paracelsus, established the primary principle of toxicology when he wrote that all substances are poisonous; there is none which is not a poison. The right dose differentiates a poison and a remedy. To paraphrase Paracelsus, it is the dose that makes the poison. This explains why one aspirin may relieve your headache but a bottle of aspirin might put you in the hospital.

Unfortunately, the logic of such a simplistic statement is ignored when one considers the Delaney Clause which prohibits the addition of any potentially carcinogenic additive to food regardless of the level. Such an approach may have been prudent in 1958 when our detection capabilities and understanding of the mechanisms of cancer were less developed. In 1995, however, our continued enforcement of the Delaney Clause represents a scientific embarrass-

ment which perpetuates misinformation and increases consumer anxiety rather than providing meaningful public health protection.

Just as an aspirin may provide a suitable remedy for a headache, H.R. 1627 provides a viable mechanism to replace Delaney with a scientifically defensible approach capable of adapting to the evolving sciences of toxicology and risk assessment. Unfortunately, your support of H.R. 1627 may be inappropriately construed by some of your constituents as an endorsement for a little bit of cancer. This notion is contradicted by the conclusions of the 1987 National Academy of Sciences report which maintained that a uniform negligible risk standard applied to both raw and processed forms could reduce rather than increase our theoretical risks from exposure to potentially carcinogenic pesticides.

I mentioned the term "theoretical" in the discussion of potential cancer risks to illustrate the complicated nature of risk assessment. Our current practice of cancer risk assessment is an imprecise one. At best, it is a crude quantitative tool to prioritize risks and allocate resources and contains a great deal of uncertainty. In practice, where uncertainties exist, scientists make conservative assumptions designed to increase the risk estimate so that errors are made on the side of safety. Such a practice, however, may lead to exaggerated estimates of the actual risks. Thus, a calculated cancer risk of one in a million using standard risk assessment techniques does not mean that one person in a million will actually develop cancer. This estimate represents an upper bound, and the actual risk may be much lower or even zero. I have submitted for the record a paper I published in 1994 which explores this issue in more detail.

Scientific advances are needed to improve risk assessment accuracy, as is evidenced by the recommendations of the 1993 National Academy Of Sciences report on pesticides in the diets of infants and children. H.R. 1627 provides the flexibility for incorporating evolving and improving science into the dietary pesticide risk assessment process by allowing the EPA to determine appropriate negligible risk criteria. Such an approach eliminates the need for a rigid and prescriptive bright line standard that is sure to become a regulatory dinosaur as improved toxicological and exposure methodologies are developed.

An important provision of H.R. 1627 allows EPA the flexibility to use the best available pesticide use and residue data to estimate exposure. Previous risk assessment efforts have commonly focused on identifying the maximum legal exposures which assume that all food items are treated with all possible pesticides, that the residues are always present at the maximum allowable levels, and that the residues in the fields are the same as those on our plates.

This approach ignores substantial evidence demonstrating that the actual use of pesticides in food crops is much less than 100 percent, that the average residues are present at small fractions of the allowable levels, and that things that you and I may do in our own kitchens such as washing, peeling, and cooking foods may serve to decrease residues dramatically. In work I have published previously, the more realistic estimates of exposures are commonly thousands to hundreds of thousands of times lower than those obtained by estimating the maximum legal exposures. H.R. 1627 will provide regulators the opportunity to more accurately estimate ex-

posures by considering realistic exposure scenarios rather than artificial and theoretical ones.

Good science makes good policy. It is now time for Congress to make appropriate changes in our Nation's food safety laws by replacing the obsolete zero-risk standard of Delaney with a workable, responsible, and modern negligible risk policy. H.R. 1627 provides an appropriate vehicle to make this change.

Thank you for providing me the opportunity to share these views.

[The prepared statement of Carl K. Winter follows:]

PREPARED STATEMENT OF CARL K. WINTER, PH.D., DIRECTOR, FOODSAFE PROGRAM, ASSOCIATE EXTENSION FOOD TOXICOLOGIST, DEPARTMENT OF FOOD SCIENCE AND TECHNOLOGY, UNIVERSITY OF CALIFORNIA, DAVIS

Good morning, Mr. Chairman and members of the Subcommittee. I am Dr. Carl Winter and I am a food toxicologist on the faculty of the Department of Food Science and Technology at the University of California at Davis. I am also the Director of the University's FoodSafe Program, which was established in 1992 to facilitate the development and sharing of research-based food safety information. The program receives no funding from the agricultural, chemical, or food industries. The views expressed today are my own and do not represent an official position of the University of California.

I am pleased to see that the committee is seriously considering H.R. 1627 as a replacement for the anachronistic Delaney Clause. Back in the 16th century, the Swiss physician Phillipus Aureolus Theophrastus Bombastus von Hohenheim, also known as Paracelsus, established the primary principle of toxicology when he wrote that "all substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy." To paraphrase Paracelsus, it is the dose that makes the poison. This explains why one aspirin may relieve your headache, but a bottle of aspirin might put you in the hospital. Unfortunately, the logic of such a simplistic statement is ignored when one considers the Delaney Clause, which prohibits the addition of any potentially carcinogenic additive to food, regardless of the level. Such an approach may have been prudent in 1958 when our detection capabilities and understanding of the mechanisms of cancer were less developed. In 1995, however, our continued enforcement of the Delaney Clause represents an embarrassment which undermines our nation's scientific integrity and scientific literacy.

Just as an aspirin may provide a suitable remedy for a headache, H.R. 1627 provides a viable mechanism to replace Delaney with a scientifically-defensible approach capable of adapting to the evolving sciences of toxicology and risk assessment. Unfortunately, support of H.R. 1627 may be inappropriately construed by some as an endorsement for "a little bit of cancer." This notion is contradicted by the conclusions of the 1987 National Research Council report (1) which maintained that a uniform negligible risk standard applied to both raw and processed foods could *reduce* rather than increase, our theoretical risks from exposure to potentially carcinogenic pesticides.

I mention the term "theoretical" in the discussion of potential cancer risks to illustrate the complicated nature of risk assessment. Our current practice of cancer risk assessment is an imprecise process requiring a series of judgments based on both scientific and philosophical grounds. At best, it is a crude quantitative tool to prioritize risks and allocate resources and contains a great deal of uncertainty. In practice, where uncertainties exist, scientists make conservative assumptions designed to increase the risk estimate so that errors are made on the side of safety. Such a practice, however, may lead to exaggerated estimates of the actual risks. Thus, a calculated cancer risk of one in a million using standard risk assessment techniques does not mean that one person in a million will actually develop cancer; this estimate represents an upper bound and the actual risk may be much lower or even zero. I have submitted for the record a paper I published in 1994 which explores this issue in more detail (2).

The uncertainty inherent in the risk assessment process must be appreciated if appropriate science-based policies are to be developed. Scientific advances are needed to improve risk assessment accuracy, and H.R. 1627 provides the flexibility for incorporation of evolving and improving science into the dietary pesticide risk assessment process by allowing the EPA to determine appropriate negligible risk criteria. Such an approach eliminates the need for a rigid and prescriptive "bright-line"

standard that is sure to become a regulatory dinosaur as improved toxicological and exposure methodologies are developed.

An important provision of H.R. 1627 is that it allows EPA the flexibility to use the best available pesticide use and residue data to estimate exposure. Previous risk assessment efforts have commonly focused upon identifying the maximum legal exposures (theoretical maximum residue contributions) which assume that all food items are treated with all possible pesticides, that the residues are always present at the maximum allowable levels, and that the residues in the fields are the same as those on our plates (1,3). This approach ignores substantial evidence demonstrating that the actual use of pesticides on food crops is much less than 100 percent, that the average residues are present at small fractions of the allowable levels, and that things that you and I may do in our own kitchens, such as washing, peeling, and cooking foods may serve to decrease residues dramatically. In work I have published previously (4), the more realistic estimates of exposures are commonly thousands to hundreds of thousands times lower than those obtained by estimating the maximum legal exposures. H.R. 1627 will provide regulators the opportunity to more accurately estimate exposures by considering realistic exposure scenarios rather than artificial and theoretical ones.

From a toxicological standpoint, it is critical that potential health *risks* from pesticide residues be balanced with potential health *benefits*. The use of pesticides may enable consumers to purchase an abundance of fruits and vegetables at affordable costs, encouraging the liberal consumption of these foods, which have been shown to *decrease* certain types of cancer and heart disease. The Delaney Clause, unfortunately, may eliminate many pesticide uses without adequate scientific justification leading to a less abundant and more expensive food supply; such a finding argues strongly for the passage of H.R. 1627. On a more specific note, the use of some pesticides may limit the preduction of naturally-occurring toxins of far greater toxicological concern. Many fungi, for example, may produce significant levels of carcinogenic mycotoxins such as aflatoxins if not controlled by fungicides. The recent discovery of mycotoxins known as fumonisins (5) and *Alternaria* toxins (6) in the food supply amplify the need to control the production of such toxins by various techniques, including pesticides.

In summary, it's now time for Congress to make appropriate changes in our nation's food safety laws by replacing the obsolete zero risk standard of Delaney with a workable, responsible, and modern negligible risk policy. H.R. 1627 provides the appropriate vehicle to make this change.

Thank you for providing me the opportunity to share these views.

Mr. BILIRAKIS. Thank you very much, Doctor.

Mr. Gianessi.

STATEMENT OF LEONARD P. GIANESSI

Mr. GIANESSI. Thank you, Mr. Chairman.

My name is Leonard Gianessi. I am a senior research associate at the National Center for Food and Agricultural Policy, an independent nonprofit research organization here in Washington.

As a result of court rulings, EPA has announced its intention of canceling 80 uses of pesticides that violate the Delaney Clause requirements. My organization has recently completed a study which calculates the potential economic impact of this Delaney enforcement to be over $400 million a year. This study will be released here next Tuesday, and we will make a copy of the study available for your record. Let me provide some examples.

In the U.S., potato growers are facing an epidemic of the potato blight that caused the Irish potato famine of the last century. The fungus that causes potato blight recently mutated and is much more difficult to control. Over the past few years U.S. potato growers have increased their use of fungicides to control this problem. The two fungicides that are the mainstays of controlling potato blight are mancozeb and chlorothalonil. EPA has listed both of these chemicals to be canceled under their strict interpretation of

the Delaney Clause. Lost potato yields and increased production costs totally $100 million per year for potatoes are the likely result.

Rice growers stand to lose the only fungicide that is effective in controlling rice blast, which is a disease in the Delta States. In an average year U.S. growers would lose about $27 million of rice to this disease. Peanut growers in Virginia, North Carolina, Georgia, and Alabama would lose about $18 million of peanuts every year due to competition with weeds due to the use of less effective chemical herbicides. Citrus growers in Florida would lose $14 million of oranges every year to a disease that could not be controlled without a Delaney targeted fungicide.

But these increased yield losses are just half the story. In addition, growers will be spending substantially more for alternative chemicals. There are alternative chemicals for many of the Delaney targeted uses in many cases. They work as well, but they cost more. We estimate that cotton growers will spend about $40 million per year for alternative pesticides as a result of Delaney. California grape growers are likely to spend $22 million year; citrus growers, $5 million more. So on the whole there will be lost yields and considerably greater expenditures for pesticides as a result of the Delaney actions.

Delaney enforcement actions do not consider benefits at all, and some of the targeted pesticide uses are key to successful integrated pest management programs. Let me give you an example.

In California grape vineyards have several natural predators of the insect. Certain beneficial insects exist in these vineyards that eat some of insect pests of grapes. Now when California grape growers have to use a chemical they choose a chemical that is selective in that it kills harmful mites but doesn't damage the beneficial insects. But this pesticide, propargite, is listed for a ban under EPA's Delaney Clause enforcement. Growers will be forced into using alternatives that are not so gentle on these predators. The Department of Agriculture, in a report that they issued just last year, estimated that without this chemical the use of insecticides in California grape vineyards would double. Grape growers in California would be forced into using another chemical, spraying more, spending more for pesticides, and disrupting their integrated program.

Now one of the first actions that EPA took in enforcing Delaney was to cancel certain emergency registrations for which there were Delaney concerns. What would have been the results? In the Northwest, mint growers were granted the emergency use of an herbicide to control weeds for which there were no other registered means of control. EPA then revoked the emergency registration because of Delaney. Mint yields in Oregon declined by 13 percent in the first year, 1993.

In North Carolina EPA acknowledged an emergency condition for apple growers by providing a registration for a fungicide to control a disease that had just recently entered the United States and for which there was no adequate control. Then EPA canceled that pesticide because of a Delaney concern. 1994 was a very wet year in North Carolina. The disease flourished in the State. Growers had no way of controlling this disease. 1994 apple production in North Carolina was about 50 million pounds below normal production

level. The fungus, the disease, got about 50 million pounds of apples in North Carolina because of Delaney enforcement.

The Delaney Clause is a strict requirement. It allows no consideration of the benefits of a chemical use. EPA is moving to cancel 80 pesticide uses. If that policy is carried out there will be substantial losses to U.S. agriculture.

Thank you.

[The prepared statement of Leonard P. Gianessi follows:]

PREPARED STATEMENT OF LEONARD P. GIANESSI, SENIOR RESEARCH ASSOCIATE, NATIONAL CENTER FOR FOOD AND AGRICULTURAL POLICY

My name is Leonard Gianessi. I am a Senior Research Associate at the National Center for Food and Agricultural Policy—a small, independent, non-profit research organization here in Washington. My comments address the potential economic impacts of Delaney Clause enforcement on U.S. agriculture. As a result of court rulings, EPA has announced its intention of canceling certain uses of pesticides that violate Delaney Clause requirements. H.R. 1627 would remove the threat of pesticide cancellations under Delaney by specifically excluding pesticides from consideration as food additives. EPA has identified approximately 85 pesticide uses that would be canceled under the current strict interpretation of Delaney. My organization has conducted a study which calculates the potential economic impact to be over 400 million dollars a year. This study will be released here next Tuesday. We will make a copy of the study available for your hearing record.

The basic premise of our study is that if farmers are using a chemical on a large number of crop acres, they are doing so because the chemical is the most cost-effective solution to a pest control problem. Thus, if the chemical were to be removed through government action, growers would select the next-best alternative, often at considerably greater expense or loss in effectiveness. The loss of these chemicals will result in higher costs of control for growers, lower yields, and a disruption of pest management strategies—some of which are designed to reduce pesticide use. Let me provide some examples.

LOWER YIELDS

In the U.S., potato growers are facing an epidemic of the potato blight that caused the Irish Potato Famine last century. The fungus that causes potato blight recently mutated and is much more difficult to control. Over the past few years, potato growers in Pennsylvania, Maine and Wisconsin have increased their use of fungicides to control this disease. The two fungicides that are the mainstay of potato blight control are Mancozeb and Chlorothalonil. Both of these chemicals would be canceled for use by potato growers under a strict interpretation of the Delaney Clause. U.S. potato growers would be left with less effective, more expensive materials for controlling this increasingly virulent disease problem. Lost potato yields and increased production costs totaling $100 million per year are the likely result.

Rice growers in the Delta states of Mississippi, Louisiana, and Arkansas are facing an epidemic of a disease called "rice blast," which literally "blasts" the rice kernel out of the rice plants. In uncontrolled rice blast epidemics, rice yields decline by 75-80%. Rice growers stand to lose the *only* fungicide that is effective in controlling rice blast as a result of a strict interpretation of the Delaney Clause. In an average year for rice blast, U.S. growers would lose $27 million of rice to the disease. With regard to both potato blight and rice blast, we're talking about virulent, serious diseases of plants with trillions of disease spores floating around in the environment. Today, growers are controlling these diseases with the use of chemicals. With a strict enforcement of Delaney, effective control disappears; yield losses increase; rice and potato plants will become diseased and rot.

Increased losses of apple production to uncontrolled diseases would also be about $100 million as a result of Delaney actions. Several years ago, EPA concluded a Special Review of the EBDC fungicides. EPA was highly complimentary to the apple industry, which had conducted studies of pesticide residues and found that they were negligible or non-existent. So EPA was convinced that continued use of the EBDC fungicides would pose no significant risk *and* that the benefits were substantial. Today, those very same registrations are targeted for cancellation due to Delaney concerns. Nothing has changed. The risks of the EBDC fungicides on apples *are* negligible—are below negligible—and the benefits are substantial.

Our study goes crop-by-crop and State-by-State and delineates the crop losses that would occur under the potential Delaney enforcement.

- Peanut growers in Virginia, North Carolina, Georgia and Alabama would lose about $18 million of peanuts due to competition with weeds, due to the use of less-effective chemical herbicides.
- Plum growers in California would lose 10% of their plums on 22% of their acreage due to the feeding of mites that would be less effectively controlled with alternatives.
- Citrus growers in Florida would lose $14 million of oranges to a disease that could not be controlled without a Delaney-targeted fungicide.
- Tomato growers in Florida would lose $17 million in tomato production to a disease that could not be controlled without a Delaney-listed fungicide.

HIGHER COSTS

Increased yield losses are only half the story. In addition, growers will be spending more for alternative chemicals. There are alternative chemicals for many uses that are targeted by Delaney Clause enforcement. In many cases, they would work as well, but they are more expensive. Thus, growers are currently using the less-expensive chemicals that are targeted by Delaney.

We estimate that cotton growers will spend $40 million more per year for alternative pesticides as a result of Delaney. California grape growers are likely to spend $9 million more per year for alternative fungicides to control mildews. Citrus growers are likely to spend $5 million more in pesticide purchases as a result of Delaney. Wheat growers in Arkansas, Louisiana, Kentucky and Tennessee are likely to spend $2 million more to control diseases as a result of Delaney. So, on the whole, there will be much greater expenditures for pesticides as a result of Delaney actions that remove cheaper compounds.

DISRUPTION OF PRODUCTION PRACTICES

Delaney enforcement actions do not consider benefits at all. Some of the targeted pesticide uses are key to successful ongoing IPM (Integrated Pest Management) Programs. Their cancellation will result in negative impacts on the IPM programs. Let me give you an example:

In California grape vineyards, several natural predators exist. Certain beneficial insects eat some of the insect pests of grapes. So grape growers don't have to use chemicals constantly to control certain pests. When California grape growers have to control mites, they choose Propargite because this chemical is selective—it kills the harmful mites and does not damage the natural predatory insects. Propargite use on grapes is listed for a ban under the Delaney Clause enforcement. Growers will be forced into using alternatives that are not so gentle on the predators. The U.S. Department of Agriculture, in a report issued in 1994, estimated that without Propargite—the number of insecticide applications in California grape vineyards would double. Grape growers in California would be spraying more often, spending more for pesticides, and killing natural predators. All because of a cancellation due to Delaney concerns.

PRESENT IMPACTS

Now these are all predictions. These predictions may not come about. EPA may make administrative decisions that result in some of the targeted uses being taken off the list. EPA may grant new registrations, or emergency registration of products that would mitigate the negative consequences of canceling these pesticides. I know that there are some skeptics out there who claim that the negative consequences never seem to materialize when EPA cancels a pesticide. Let me assure you that some negative effects have already resulted from EPA Delaney actions.

One of the first actions that EPA took with regard to Delaney was to cancel emergency registrations of compounds for which there were Delaney concerns. EPA took this action in 1993. Basically, EPA had concluded that growers in certain areas of the country faced emergency pest control problems which the emergency registrations would alleviate. EPA granted the emergency registrations under Section 18 of FIFRA and then revoked them because of Delaney concerns. What have been the results?

- In the Northwest, mint growers were granted the emergency use of an herbicide to control weeds for which there were no other means of control. EPA then revoked the registration because of Delaney. Mint yields in Oregon declined by 13% in 1993—a loss of 625,000 pounds of mint oil due to uncontrolled weeds which could have been controlled if the emergency registration was allowed.

In North Carolina, EPA acknowledged an emergency condition for apple growers by providing a registration for a fungicide to control a disease that had just recently

entered the U.S. and for which there were no adequate controls. EPA granted this registration for 1992 and also for 1993, but then revoked it for 1993. Fortunately, 1993 was a dry year, and the fungus didn't do well. So North Carolina apple production did not decline in 1993. However, 1994 was a very wet year. The fungus flourished, and growers were left with no effective means of control. 1994 apple production in North Carolina was about 50 million pounds below the normal production level.

The Delaney Clause is a strict requirement that allows no consideration of the benefits of a chemical use. EPA is moving to cancel 85 pesticide uses for which the risks are truly negligible. If that policy is carried out, lost benefits to U.S. agriculture will be greater than $400 million a year in lost production and increased pesticide costs.

Mr. BILIRAKIS. Thank you, Mr. Gianessi, for sharing those stories with us.

Dr. Gray.

STATEMENT OF GEORGE M. GRAY

Mr. GRAY. Mr. Chairman, members of the committee, thank you for the opportunity to come before you today to support the Food Quality Protection Act of 1995.

I'm George Gray, deputy director of the Harvard Center for Risk Analysis at the Harvard School of Public Health. As a toxicologist, risk analyst, and public health professional, there are three points I would like to make today.

First, the Delaney Clause is slowing progress toward reducing risks from pesticide use. You will hear many times that the Delaney Clause is scientifically and practically nonsensical. This is true. But not only does it not make sense, the Delaney Clause is putting consumers and farmers at risk. New generations of pesticides are much safer for both humans and the environment than those that came before. Even these pesticides, however, when fed to animals at very high doses, may be considered carcinogens. The Delaney Clause, by denying farmers the use of these new materials, is prolonging the use of more dangerous older pesticides.

In addition to keeping newer pesticides out of the hands of farmers, the Delaney Clause may be causing harm by its focus on cancer. It may be that the EPA and the farming community would rather see a weakly carcinogenic pesticide with very low risk used in place of a pesticide with clear neurotoxicity or reproductive toxicity. Similarly, the focus on cancer risk primarily to consumers may preclude the introduction of pesticides that could reduce risks to farmers or farm workers. I believe that the negligible risk standard developed in H.R. 1627 will allow EPA to move toward lower risk methods of crop protection.

My second point is that risk assessment is the tool for ensuring the safe use of pesticides. I'm a strong believer in risk assessment. Advances in the science and the methods of risk assessment are improving the quality of information that we can bring to bear in questions of human and environmental health. Risk assessment for pesticide regulation must make good use of all available science, assess all types of risk, not just cancer, and should evaluate risks to consumers, workers, and the environment.

Just for instance, a new pesticide product that reduces risk to consumers may produce harm to farmers or to the environment. As an example, consider DDT, a pesticide of very low toxicity to humans, which was banned in 1972 due to concerns about toxicity to

fish and birds. The most common substitute for DDT, parathion, poses less risks to the environment but caused many poisonings among farmers. Consideration of the risks of alternative pest control methods and the way in which those risks can be managed is key to the safe use of pesticides.

I fully support the goals of H.R. 1627 to develop a better understanding of differences in pesticide exposure for children and to consider this in tolerance setting. However, I urge that the consideration of differences in exposure not stop with children. Of course we are concerned about that part of our population, children, who consume more apple juice than average, but shouldn't we also be concerned about the part of our population that consumes more prune juice than average? Different patterns of food consumption in different age groups, ethnic groups, or regions of the country should not be ignored.

I also commend the authors of H.R. 1627 for recognizing that differences in risk can be due not only to differences in exposure but also differences in susceptibility to the toxic effect of pesticides. Again, the focus on children is good, but I would urge that better research and risk assessment methods be encouraged for all groups. For instance, toxicologists know that adult rats are much more sensitive to the acute toxic effects of DDT than are newborns. Let's make sure that we consider all members of the population.

My final point is that benefits, both economic and health related, must be considered as part of a sound pesticide policy. Congress recommended when first writing FIFRA and FFDCA that the many benefits of pesticide use must be considered when regulating their use. I urge that the sections of H.R. 1627 dealing with benefits make explicit the consideration of benefits to farmers, consumers, and the environment, and it must also be recognized that these benefits can be economic or health related, better health due to better diet and the reduction of risk from other pesticides or the risks induced by pests. Others can speak more directly to the clear economic benefits of pesticides, but I would like to remind you of the health and risk reduction benefits of pesticides.

Pesticides make an important contribution to American public health. For example, fruits that are inadequately protected against pests have been shown to have lower nutritional value—for example, less vitamin C in apples than fruits that have been protected. In addition, by lowering the price of producing food, pesticides lower the cost of food for consumers. We know that eating fresh fruits and vegetables can protect against cancer, heart disease, and other ailments, and we must be concerned that higher prices will reduce consumption of these health protective foods.

It is frequently recognized that pesticides can reduce the risk from natural toxins. For example, the risks of fungicide use on peanuts must be weighed against the benefit of reducing the carcinogenic risk of aflatoxin that would grow in its absence.

It is less often recognized that some pesticides have the benefits of reducing risks to farmers, consumers, and the environment. The benefit to consumers arises when a less risky pesticide takes the place of a more risky alternative. The benefit for farmers is similar. We must consider risk reduction for farmers as an important benefit of pesticides.

For the environment we must recognize that use of pesticides has reduced the number of acres of land required to grow food in this country, increased the use of land to grow the same amount of food. The consequence of the losses on pesticides is a benefit or in fact a disbenefit that should be considered. The benefit is illustrated by a case study that I did for a book for the Harvard Center for Risk Analysis in which the primary fungicide——

Mr. BILIRAKIS. Would you finish up please, Doctor?

Mr. GRAY. The primary fungicide used to control mildew on lettuce also controlled several other fungal pests. Since no alternative did the same, loss of this fungicide would have required at least two additional pesticides to control fungi in lettuce, thereby increasing the total environmental burden of pesticides.

In conclusion, I would like to say that the bill before you today will provide a clear benefit to public health. Elimination of the Delaney Clause through a uniform negligible risk standard will restore scientific credibility to pesticide policy, prevent the problem of the use of new, safer pesticides being denied to farmers, and lend the regulatory preoccupation with cancer sometimes to the exclusion of other risks to the health of farmers and consumers.

Use of risk assessment especially with a focus on variability in exposure and differences in susceptibility will ensure pesticide use will be safe for all members of society. An explicit consideration of benefits will make sure that the economic and health gains from pesticides will not be ignored.

Thank you very much.

[The prepared statement of George M. Gray follows:]

PREPARED STATEMENT OF GEORGE M. GRAY, PH.D., DEPUTY DIRECTOR, HARVARD CENTER FOR RISK ANALYSIS, HARVARD SCHOOL OF PUBLIC HEALTH

Mr. Chairman, members of the committee, thank you for the opportunity to come before you today to support H.R. 1627, *The Food Quality Protection Act of 1995.*

I am George Gray, Deputy Director of the Harvard Center for Risk Analysis at the Harvard School of Public Health. As a toxicologist, risk analyst and public health professional I have 3 key points that I would like make today. First, the Delaney Clause is slowing progress toward reducing risk from pesticide use. Second, risk assessment is the tool for ensuring the safe use of pesticides. Finally, benefits—both economic and health related—must be considered as part of a sound pesticide policy. I will now address each in turn.

The Delaney Clause is Slowing Progress Toward Reducing Risk From Pesticide Use

You will hear many times today that the Delaney Clause scientifically and practically makes no sense. This is true. Yet not only does the Delaney Clause not make sense, it is also putting consumers and farmers at risk.

New generations of pesticides are much safer for both humans and the environment than those that came before. Even these pesticides, however, when fed to animals at extremely high doses may be considered carcinogens. Many of these new pesticides are only weakly carcinogenic, causing tumors only when present as several percent of an animal's diet. The Delaney Clause, by denying farmers the use of these new materials, is prolonging the use of older, often more dangerous, pesticides. I found an example of this in a case study I wrote for an upcoming book from the Harvard Center for Risk Analysis. The case study focused on control of the fungal disease downy milder on lettuce. It was clear in this case that the Delaney Clause prevented use of a less risky fungicide leaving only older pesticides as fungal control options.

In addition to keeping newer, safer, pesticides out of the hands of farmers the Delaney Clause may harm health by its focus on cancer. It may be that the EPA, and the farming community, would rather see a weakly carcinogenic pesticide with very low risk used in place of a pesticide with clear neurotoxicity or reproductive toxicity. Similarly, the focus on cancer risk, primarily to consumers, may preclude introduction of pesticides that could reduce risk to farmers and farm workers.

I believe that the negligible risk standard developed in H.R. 1627 will allow EPA to move toward lower risk methods of crop protection. In addition, it will ensure that all types of risk, not just cancer risk, are considered for both consumers and farm workers.

Risk Assessment is the Tool for Ensuring the Safe Use of Pesticides

I am a strong believer in risk assessment. Advances in the science and methods of risk assessment are improving the quality of the information we can bring to bear on questions of human and environmental health.

Risk assessment for pesticide regulation must make good use of all available science, assess all types of risk, not only cancer, and should evaluate risks to consumers, workers, and the environment. It is important that regulators have the flexibility to consider risks to not only consumers, but workers and the environment as well. For instance, new pesticide products that reduce risk to consumers may harm workers or the environment. As an example consider DDT, a pesticide of very low acute toxicity to humans which was banned in 1972 due to concerns about toxicity to fish and birds. The most common substitute for DDT, parathion, posed less risk to the environment but caused many poisonings among farmers. Consideration of the risks of alternative pest control methods, and the ways in which those risks can be managed, is key to safe use of pesticides.

I fully support the goals of H.R. 1627 to develop better understanding of differences in pesticide exposure for children and to consider this in tolerance setting. However, I would urge that consideration of differences in exposure not stop with children. Different patterns of food consumption in different age groups, ethnic groups, or regions of the country should not be ignored.

I commend the authors of H.R. 1627 for recognizing that differences in risk can be due not only to differences in exposure but also to differences in susceptibility to the toxic effects of pesticides. Again, the focus on children is good, but I would urge that better research and risk assessment methods be encouraged for all age groups. For instance, toxicologists know that adult rats are much more sensitive to the acute toxicity of DDT than are newborns. Lets make sure we consider all members of the population.

Risk assessment is the proper tool for using scientific information to support the safe use of pesticides. Conduct and use of risk assessment must remain flexible to allow EPA to respond to advanced in science and to use its judgment in evaluating pesticide use. H.R. 1627 will lead to improvements in the information developed by risk assessment, allowing better regulatory decisions.

Benefits—Both Economic and Health Related—Must be Considered as Part of a Sound Pesticide Policy

Congress recognized when first writing FIFRA and the FFDCA that the many benefits of pesticide use must be considered when regulating their use. I urge that the sections of H.R. 1627 dealing with benefits make explicit the consideration of benefits to farmers, consumers, and the environment. It must also be recognized that benefits can be economic, better health due to diet, and roduction of risk from other pesticides or hazards induced by pests.

Others can speak more directly to the clear economic benefits of pesticide use but I would like to remind you of the health and risk reduction benefits of many pesticides.

Pesticides make an important contribution to American public health. For example, fruits that are inadequately protected against pests have been shown to have lower nutritional value, including less Vitamin C in apples, than fruits protected with pesticides. In addition, by lowering the price of producing food pesticides lower the costs of food for consumers. We know that eating fresh fruits and vegetables can protect against cancer, heart disease and other ailments and we must be concerned that higher prices will reduce consumption of these health protective foods.

It is frequently recognized that pesticides can reduce the risks from natural toxins. For example, the risks of fungicide use on peanuts must be weighed against the benefit of reducing the carcinogenic risk of aflatoxin produced by fungi in its absence. It is less often recognized that some pesticides have the benefit of reducing risk to consumers, farmers, and the environment. The benefit to consumers arises when a less risky pesticide takes the place of a more risky alternative. The benefit for farmers is similar. We must consider risk reduction for farmers as an important benefit of pesticide use. Even organic farmers are at risk. Organic farmers employ natural pesticides that can be just as toxic and carcinogenic as synthetic pesticides even though they are less thoroughly tested for toxicity. For example, in California, the state with the most thorough system for reporting occupational disease caused by pesticides, the pesticide with the highest number of reported illnesses in the pe-

riod 1984-1990 was sulfur, a pesticide widely used on "organic" farms. Use of pesticides has reduced the number of acres of land required to grow food in this country. Increased use of land to grow the same amount of food, a consequence of loss of some pesticides, should be considered in benefit assessment. Another environmental benefit is illustrated by an example from my lettuce case study. The primary fungicide used to control downy mildew on lettuce also controlled several other fungal pests. Since no alternative did the same, loss of this fungicide would have required at least two additional pesticides to control fungi on lettuce thereby increasing the total environmental burden of pesticides.

I would also encourage the development of better benefit data to aid decision making. For example, is the already considerable accident risk to farmers increased if more land tilling replaces pesticide use? For consumers, are the economic benefits of pesticide use uniform or are some groups more vulnerable to price increases? For the environment, would the use of one broad spectrum pesticide reduce the pesticide load and potential impact on the environment. We must cast our net widely in considering benefits to ensure appropriate regulation of pesticides.

Conclusion

The bill before you today, H.R. 1627, will provide a clear benefit to public health. Elimination of the Delaney Clause, through a uniform negligible risk standard, will restore scientific credibility to pesticide policy, prevent the problem of the use of new, safer pesticides being denied to farmers, and will end regulatory preoccupation with cancer, sometimes to the exclusion of other risks to the health of consumers and farmers. Use of risk assessment, especially with a focus on variability in exposure and differences in susceptibility, will ensure that pesticide use will be safe for all members of society. Explicit consideration of benefits will make sure that the economic and health gains from pesticide use will not be ignored.

Thank you very much for the opportunity to testify today.

Mr. BILIRAKIS. Thank you, Doctor.

I'll start off the questioning. Dr. Gray, you are a medical doctor?

Mr. GRAY. No, I'm not; I'm a toxicologist.

Mr. BILIRAKIS. You are a toxicologist, and you are with the Harvard School of Public Health. How long have you been with them?

Mr. GRAY. Seven years.

Mr. BILIRAKIS. Seven years?

Mr. GRAY. Yes.

Mr. BILIRAKIS. Now, Dr. Winter, are you a medical doctor?

Mr. WINTER. No. I'm also a toxicologist.

Mr. BILIRAKIS. They say you should always know the answer to every question before you ask the question. I guess I should have known the answers.

I feel certain that you three gentlemen care every bit as much about public health as we do—that is your field after all— and you care about the effect of pesticides, the adverse effect that they could have upon not only children but, as you indicated, the elderly and the rest of us somewhere in between. I always consider myself somewhere in between regardless of what age I might reach. You have no axes to grind as far as I can see.

Do you see a conflict between H.R. 1627 and the public health? I've indicated an interest, in sitting down with the administration and working out some of these areas. But is there a conflict between public health, the health of children, the health of the elderly, the health of people in general, and what we are trying to do in H.R. 1627?

Mr. GRAY. I certainly do not think that there is. In fact, I believe that the use of a uniform negligible risk standard is generally accepted in the scientific community and in fact was put forth by the National Academy of Sciences as a way to really make sure that we are using pesticides in the safest way possible.

Mr. BILIRAKIS. Getting to some of the testimony given by Dr. Goldman, should the Congress be more detailed—I mean are we better scientists than EPA may have on it staff?

Mr. WINTER. I would certainly commend EPA for their scientific leadership in this area. I think they certainly have the tools and the people to apply the best science that is available provided that they have the resources necessary to allow them to use the best data, to generate the best data, to use the best models. I think provided that they have those resources and that there is some understanding about maybe some specific language, the issue of negligible risk versus reasonable certainty of no harm can actually have some differences, and I think that is something that hopefully can be worked out with the committee.

Mr. BILIRAKIS. Certainly whatever resources they have, they have got to have more than we have.

Mr. WINTER. Right.

Mr. BILIRAKIS. I think you would agree.

Mr. WINTER. I think they are highly qualified, they are the leaders in this area, and they are the best people to do this type of risk assessment.

Mr. BILIRAKIS. The administration points out that H.R. 1627 is responsive to the NAS report on pesticides in the diets of infants and children and that it provides measures to ensure that needed information about children's diets and pesticide residues are available. However, the administration would like to see requirements that this information, along with information about susceptibility, be used in developing tolerances. Could you please comment?

Mr. WINTER. From my perspective, I think that that information can and should be used, and I don't see that H.R. 1627 in any way precludes EPA from using that data.

Mr. BILIRAKIS. Mr. Gianessi?

Mr. GIANESSI. I agree with that.

Mr. BILIRAKIS. Dr. Gray?

Mr. GRAY. I do as well. It seems to me that it is explicitly written in H.R. 1627 that the administrator shall take account of a variety of things, including risks to particular subgroups, especially children.

Mr. BILIRAKIS. Current law seems to be silent insofar as children are concerned and H.R. 1627, according to some of the questioners earlier today, is not as strong in that regard. Is there anything that would preclude EPA today, from expanding basically its role as a regulator to basically go into the children's safety area?

Mr. WINTER. I am unaware of anything.

Mr. BILIRAKIS. There is not, is there?

Mr. GRAY. There is not, and in fact in many cases they do look at risks specifically for children now. In fact, by giving them broad discretion it has been allowed.

Mr. BILIRAKIS. Thank you. Thank you gentlemen. My time has expired. Thank you so much for your viewpoints.

Let's see. Mr. Burr, I guess, would be first.

Mr. BURR. Thank you, Mr. Chairman.

Dr. Winter, 37 years ago—and I'm assuming that you are over 37——

Mr. WINTER. I was born in the year of Delaney.

Mr. BURR. Okay—could you have come up with the same conclusions as you have today about your comments?

Mr. WINTER. Well, I think 37 years ago, as I mentioned, Paracelsus told us back in the 16th century that the dose makes the poison. I think we have certainly come much further in the past 37 years in terms of understanding how chemicals may cause cancer as well as being able to detect chemicals in the environment. I think what was possibly prudent in 1958 certainly is obsolete now.

Mr. BURR. So the technology exists today for us to understand the effects much better than they were 37 years ago?

Mr. WINTER. Absolutely.

Mr. BURR. And I think all of you have commented on the NSA report, but let me—you mentioned ranges, and we have certainly talked with the EPA about the tolerance levels and this type of thing. Science is not exact, there is a need for a range, and I think we err on the side of safety in every case, and can you just comment a little bit about the need for a range and where that target should be in that range?

Mr. WINTER. Okay. That is a great question. As one toxicologist, I have my philosophy. I think one of the major principles of toxicology today is that for every Ph.D., there is an equal and opposite Ph.D., and as a result of that we will see a wide variety of views.

I think it is very prudent to make sure that when we deal with uncertainty, that we do try to err on the side of safety. However, there comes a point in which the calculations of risk take on magnification of so many uncertainty factors that the ultimate number that comes out of a risk assessment has very little relationship to the real world and, if not understood in its proper context, is subject to misrepresentation, which may ultimately lead to some bad policy.

I have included for the record a publication that I wrote in 1994 which goes into much more detail about the uncertainties, the need to correct for them, and also the need to understand them.

Mr. BURR. Thank you.

Mr. Gianessi, Dr. Goldman said consumers would not feel the economic impact if there were not a change in Delaney, and I think she alluded to the fact that if there was a change in Delaney. Now you talked about economics a little bit. Can you expand as to what the impact would be?

I happen to be from North Carolina and you used quite a few examples of North Carolina.

Mr. GIANESSI. Right. I think what the doctor said was that her economists didn't calculate the results through to the consumer level, that the way the EPA analysis is done is to go through and calculate in a similar fashion what we have done, the potential yield losses and the potential cost increases in terms of increased expenditures for pesticides. We don't have the economic models to go all the way through to consumer levels for many of these crops.

The other wild card in a lot of these calculations is, what do you assume about imports? If you allow imports to come in freely as substitutes, if you allow shifts in production around the United States, many of these economic effects would be mitigated. But on the other hand, these—we try as toxicologists in terms of coming

up with some proxy to let you know that there would be some economic effect.

Mr. BURR. Let me use your example of apples in North Carolina. The yield was down 50 percent from an apple fungus.

Mr. GIANESSI. Right.

Mr. BURR. Would common sense tell me that the price of apples was going to go up if I go to buy them?

Mr. GIANESSI. Well, in North Carolina those were Red Delicious apples. I think you are still going to see Red Delicious apples in all those supermarkets in North Carolina. They are probably not produced in North Carolina, they are probably coming from Washington and other States. They may be priced about the same. They are not North Carolina apples. Growers down there would be taking losses, workers who pick apples in North Carolina would be taking losses, packers down there would be taking losses, so in that case we would expect, because it is a national crop, that there are localized economic effects, but probably not a price increase.

Mr. BURR. Okay.

Dr. Gray, you talked about the fact that as we substitute pesticides, let's say that 80 some pesticides are taken off the market by the EPA because of the court decision, that in fact we have some alternatives that are out there, but, under varying usages or the amount that is used, that the results as far as health could be worse. Was that a correct understanding on my part?

Mr. GRAY. It certainly was, and in fact that echoes the quote I think used from Science magazine from Dr. Goldman that it is entirely possible that substitution can actually increase risks to public health.

There is the example of removing something from Delaney because of concerns that carcinogenesis could lead to more widespread use of something with some other toxic effect or something that might have potential harmful effects on the environment.

Mr. BURR. So just to follow up real quick, Mr. Chairman, if we substitute a chemical that works 75 percent as well as the last one, is it likely that a farmer, once he realizes that if he uses twice as much to get the same results, might do that even though the instructions on it say to only use X?

Mr. GRAY. I can't speak to that. I assume that farmers usually try and follow——

Mr. BURR. Well, let me try and let you speak from what would happen from the a toxicology standpoint if 75 percent were equal to 100 percent of——

Mr. GRAY. Well, we are not at all sure, but presumably you would be exceeding the tolerance on that food, the farmer would be taking a chance on having it confiscated and adulterated, and even if it weren't it would be increasing the possibility that people could be harmed.

Mr. BURR. But the habit would exist from a possible agricultural community that to achieve the same results as the pesticides before, that they might be more inclined to use those chemicals in a different way to achieve that?

Mr. GRAY. Or plant 125 percent more acres. I mean there are other ways.

Mr. BURR. Okay.

I yield back, Mr. Chairman.

Yes—not in terms of apples.

Mr. BILIRAKIS. Dr. Coburn.

Mr. COBURN. Thank you.

Dr. Gray, I want to concentrate for a minute. You are familiar with the National Academy of Sciences recommendation?

Mr. GRAY. We have been talking about two today, the Delaney paradox or children.

Mr. COBURN. Delaney.

Mr. GRAY. Delaney, yes.

Mr. COBURN. And is there anything in this bill that would keep the EPA or the FDA from following those recommendations?

Mr. GRAY. No, not at all. In fact, we would encourage them to do that.

Mr. COBURN. Okay. So having given that, I want to move to the next area which is the negligible risk standard. As a physician, if one of my patients gets something I want to know that it is not only not carcinogenic, but it is not toxic, that it is not embryogenic, I want to know all those things, and it makes sense to me that we would want to apply the same standards to all risks in terms of food additives rather than just one standard for carcinogenic and another standard for something else.

So if we discount the legal difficulties that the doctor related to, does it not make good sense to have a negligible risk standard across the board throughout as put forth in this bill?

Mr. GRAY. I think it makes a lot of sense. In fact, the legal question aside, it seems to me that as a toxicologist one of the things we try to do with pesticides with potential noncancer effects is to find a threshold level for the population below which we don't think anything will happen to anyone. That sounds to me like a negligible risk when you are below that.

Mr. COBURN. So why is that a hard position to defend if you are a toxicologist working for the EPA or the FDA?

Mr. GRAY. I don't know. It may well have something to do, as Dr. Goldman alluded, to questions of legal interpretation.

Mr. COBURN. But one of the whole purposes for this legislation is to slow down the problems of conflict over legal interpretation. So in your mind there is no reason not to use a negligible risk standard throughout the entire range of exposures?

Mr. GRAY. Absolutely not.

Mr. COBURN. Okay.

Dr. Winter, do you have any comments in regard to those two questions?

Mr. WINTER. I think from a scientific risk assessment standpoint we have two different series of ways to estimate risk depending upon whether the chemical is a carcinogen or a noncarcinogen. I can see the interpretation of a negligible risk meaning one that is insignificant, which could be possibly challenged in terms of noncarcinogenic or threshold effect, so I would hope that if a negligible risk is defined in perhaps a further version of this legislation that it really is specific, that perhaps a negligible risk meets a toxicological determination of a reasonable certainty of no harm, something like that. It is a lot of semantics, but I think from a legal standpoint it is something that does need to be clarified.

Mr. COBURN. All right. Thank you.

Mr. BILIRAKIS. The gentleman's time has expired.

Mr. Waxman.

Mr. WAXMAN. I have no questions.

Mr. BILIRAKIS. No questions.

Well, gentlemen, thank you so very much for being here today, taking time to be here. Again, your testimony was very, very helpful.

The next panel consists of Ms. Juanita Duggan, executive vice president of government affairs and public communications for the National Food Processors Association; Mr. Dennis Stolte, American Farm Bureau Federation; and Dr. Steven Ziller, vice president for science and technical affairs, Grocery Manufacturers Association of America.

Welcome, and we will start with Ms. Duggan. Your written testimony is part of the record, as you know, and if you can stay as close to 5 minutes as you can, I would appreciate it. Please proceed.

STATEMENTS OF JUANITA DUGGAN, EXECUTIVE VICE PRESIDENT FOR GOVERNMENT AFFAIRS AND PUBLIC COMMUNICATIONS, NATIONAL FOOD PROCESSORS ASSOCIATION; DENNIS STOLTE, AMERICAN FARM BUREAU FEDERATION; AND STEVEN ZILLER, VICE PRESIDENT, SCIENCE AND TECHNICAL AFFAIRS, GROCERY MANUFACTURERS ASSOCIATION OF AMERICA

Ms. DUGGAN. Thank you. I will summarize.

We appreciate the opportunity to address the important topic of pesticide regulation today. We commend your leadership in holding this hearing on proposed legislation to update and modernize our Nation's food safety laws and ensure that those laws provide strong protections for public health and the environment.

There is widespread agreement among food industry regulatory agencies, consumer organizations, and scientists alike that existing food safety law, particularly the 1950's era Delaney Clause, is outdated, unworkable, and must be reformed. However, the Court of Appeals decision in *Les* v. *Reilly* requiring a strict zero risk interpretation of the Delaney Clause and the subsequent consent decree in *California* v. *Browner* now threaten to create a food production crisis in the United States by denying farmers the use of a number of important and safe crop protection tools. This potential crisis confirms the need for legislation to reform the antiquated Delaney Clause and give EPA additional flexibility in tolerance decisionmaking.

My organization, the National Food Processors Association, strongly support H.R. 1627, the Food Quality Protection Act of 1995. It makes essential overdue improvements in our Nation's food safety laws by streamlining the pesticide cancellation and suspension process, establishing a consistent negligible risk standard for tolerances in both raw and processed food, assuring the appropriate consideration of benefits, and providing for national uniformity for tolerances meeting current safety standards.

In 1993 the National Academy of Sciences published a report that recommended the collection of data on food consumption patterns of infants and children as well as improved surveillance of

pesticide residues, development of toxicity testing procedures to evaluate the vulnerability of infants and children, and use of improved methods of risk assessment. H.R. 1627 promotes all of these goals. H.R. 1627 also permits EPA to minimize the loss of valuable minor use pesticides and to facilitate minor use registrations. We support that title as well.

Although we strongly support legislation to eliminate the Delaney Clause, it is important to bear in mind that EPA has sufficient authority under current law to regulate pesticide tolerances in a manner that would minimize the impact of the Delaney Clause. The potential devastating loss of agricultural pesticides threatened by EPA is not a necessary result of the Ninth Circuit Court decision in *Les* v. *Reilly* but of EPA's concentration and coordination policies. These policies have never been properly adopted as a regulation and, in our view, should be abandoned.

In September 1992 NFPA and other groups filed a petition urging EPA to rescind the concentration and coordination policies. The NFPA petition urges EPA to follow the language and intent of the flow-through provision of the Food, Drug, and Cosmetics Act which provides that a pesticide residue in a processed food when ready to eat is lawful as long as that residue was not greater than the tolerance for the raw commodity from which the processed food was made. The NFPA petition demonstrates that the EPA policy was never envisioned by Congress and is based upon erroneous factual information.

In February 1995, just a few months ago, the U.S. District Court in California approved a consent decree in the lawsuit regarding EPA's application of the Delaney Clause to pesticide tolerances, and under that decree EPA agreed to a rigid schedule for making tolerance revocation decisions for up to 80 potential carcinogenic pesticides in crop combinations, all of which the agency acknowledges pose no risk to public health.

If EPA retains its current policy compliance, the decree will precipitate the loss of scores of valuable pesticides. Because of this consent decree, a very real potential now exists for foods to become more expensive to grow and sell, less abundant, and poorer in quality as farmers lose many of the safe and vital crop protection tools they need. We have continued to urge EPA to grant our petition and to avoid an unnecessary food production crisis in this country. Their current new deadline, which is an extension from the original deadline, is this Friday, June 9. We hope that they will respond to the NFPA petition for once and for all and we will know what the pesticide regulatory policies are going to be for our country.

We also urge Congress to pass legislation that establishes a more rational standard that recognizes the difference between real and imagined risks.

In conclusion, we commend the subcommittee for opening a dialog on pesticide reform, but, if I might, I would like to comment on a couple of the issues that were raised by the administration.

The first issue that they raised was the question of how the negligible risk standard would apply to acute risks and whether or not it would be consistent with their current policy of reasonable certainty of no harm. I think from our point of view that is something

that is easily handled in report language and there really isn't necessarily a conflict there.

The industry supports this bill because it would move to one standard and one way of handling raw food, processed food, and all effects from eating foods with pesticide residues. So I don't think there is a real conflict there between acute and cancer risks, and I think we stand ready to work with the committee to make sure that that is well understood in report language.

With regard to the benefits concern that was raised, it seems that the administration is not willing to discuss the fact that the benefits standard in this bill is current law. It is in Section 408, and there is no evidence that this benefits standard has ever been abused by EPA's tolerance decisionmaking. This current iteration of the bill adds the term, "for consumers," which I think was intended to give it a consumer focus and to make sure that consumers are affected by the price, the availability, the quality, the nutrition supply. This is current law, and EPA uses this benefits standard now and has since 1954 in making its tolerance decisions for raw commodities. So I'm a little confused as to why they now contend that it would override the safety standard in 408, because if it were overriding the safety standard in 408 then they would be making some erroneous decisions.

Mr. BILIRAKIS. Possibly you can expand upon that during the round of questioning, but your time has expired. If you would summarize, I would appreciate it.

Ms. DUGGAN. There is just one last issue that I would like to raise, and that was the administration's question about how the Food, Drug, and Cosmetic Act and FIFRA procedures would coordinate and their concern that they would have to go through the entire FIFRA procedure in order to revoke a tolerance.

I think industry's viewpoint and one of the reasons it supports this bill that if there were no tolerances, if there were a safety problem and a tolerance couldn't be established, that there would also not be a registration so that farmers wouldn't have access to legal applications and then that food would then be illegal. The intent was to try to link those two so that food that was produced on the farm would then be legal when it got to the marketplace, and if that is not what that provision does, I think industry would have a strong desire to work with the committee and to work with the administration to clarify it.

But we stand ready to work with the committee on those issues.

[The prepared statement of Juanita Duggan follows:]

PREPARED STATEMENT OF JUANITA DUGGAN, EXECUTIVE VICE PRESIDENT FOR GOVERNMENT AFFAIRS AND COMMUNICATIONS, NATIONAL FOOD PROCESSORS ASSOCIATION

Mr. Chairman and members of the subcommittee, I am Juanita Duggan, Executive Vice President for Government Affairs and Communications 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 for holding this hearing on proposed legislation to update and modernize our nation's pesticide laws and ensure that those laws provide strong protections for public health and the environment.

NFPA is the voice of the $400 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and

provide research, technical services, education, communications and crisis management support for the association's U.S. and international members, who produce processed and packaged foods, drinks and juices.

NFPA's 500 member companies have 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 alternative 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 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 H.R. 1627, the Bliley-Roberts "Food Quality Protection Act of 1995." H.R. 1627 would make important improvements in both the federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the federal Food, Drug and Cosmetic Act (FD&C Act). It 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, H.R. 1627 contains specific provisions, which we strongly support, that would require EPA to implement procedures that ensure that pesticide tolerances adequately safeguard the health of infants and children and that would facilitate the registration of minor use pesticides.

As the Subcommittee is well aware, on June 29, 1993, the National Academy of Sciences (NAS) published a widely published report on Pesticides in the Diets of Infants and Children. The NAS Report recommends collection of additional data on food consumption patterns of infants and children, improved surveillance of pesticide residues, development of toxicity testing procedures to evaluate the vulnerability of infants and children, and use of improved methods of risk assessment to take account of the unique features of infants and children. NFPA applauds the NAS for its careful study, and we agree that better data are needed for pesticide regulatory decisions and that special emphasis should be placed on the evaluation of potential risks to infants and children. H.R. 1627 would promote both of these goals.

The growing loss of minor use pesticides for fruit and vegetable production poses a serious problem for the food industry and consumers. Minor uses are not economically attractive to the pesticide industry, and there is little incentive for pesticide producers to underwrite the high cost of reregistering minor uses under the data and fee requirements of the 1988 FIFRA Amendments. A growing number of pesticide producers are abandoning minor use registrations, without any consideration of the relative safety or benefits of those uses. H.R. 1627 would permit EPA to minimize loss of valuable minor use pesticides by establishing a scientifically defensible negligible risk standard, by requiring EPA to base its risk assessments on actual pesticide use and residue data, and by providing for appropriate consideration of pesticide benefits. H.R. 1627 also contains a set of important provisions that would facilitate minor use registrations through extension of the period of exclusive data use, extension of data submission deadlines, fee waivers and other provisions.

Although we strongly support legislation to nationalize pesticide tolerance regulation and to eliminate application of the Delaney Clause to pesticides in processed food, it is important to bear in mind that 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 for EPA to create a crisis through wholesale revocation of pesticide tolerances.

The potential devastating loss of agricultural pesticides threatened by EPA is not a necessary result of the Ninth Circuit decision in *Les* v. *Reilly* but of EPA's concentration and coordination policies. These policies have 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 posticide.

In September 1992, NFPA, along with several 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. Thus, there, is no sound legal or public policy basis for EPA to continue its concentration and coordination policies, and EPA should not be permitted to perpetuate these policies to create an artificial pesticide crisis.

In February 1995, a U.S. district court in California approved a consent decree in a lawsuit brought by California and the National Resources Council against EPA regarding the Agency's application of the Delaney Clause to pesticide tolerances. Under the decree, EPA agreed to a rigid schedule for making tolerance revocation decisions for up to 80 potential carcinogenic pesticides that the Agency acknowledges pose only a negligible risk. If EPA retains its current policy, compliance with the decree will precipitate the loss of scores of valuable pesticides. However, the consent decree does not dictate how EPA must rule on the NFPA petition. The consent decree originally required that EPA rule on the NFPA petition by April 9, 1995. The court subsequently granted EPA's request to postpone the date for ruling on the NFPA petition until June 9, 1995.

With this background, I will describe the major provisions of H.R. 1627 that we support.

1. Cancellation Procedure.

The existing FIFRA cancellation process is unduly lengthy and cumbersome, has no statutory time limit, and hampers EPA's ability to remove potentially hazardous pesticides from the market in a timely manner. Under current law, EPA must submit a proposed cancellation notice for review by USDA and undertake a notice and comment rulemaking process, followed, if requested, by a formal adjudicatory hearing and referral of questions of scientific fact to a committee of the National Academy of Sciences (NAS).

H.R. 1627 would streamline the cancellation process by eliminating the right to refer questions of scientific fact to an NAS committee, restricting cancellation hearings and establishing a one year time limit for completion of the full cancellation process. The registrant and other interested parties would retain the right to make written submissions during a specified comment period, and EPA would be required to provide opportunity for a hearing, including the right to make documentary submissions and to conduct limited cross-examination on disputed issues of material fact.

This provision would grant EPA authority to act promptly to remove unsafe pesticides from the market, and would also insure that cancellation decisions are based on a full and adequate administrative record. The decision to initiate a cancellation proceeding would require a sound scientific basis and only would be made after prior notice to USDA, FDA and the registrant.

The one year time limit on the cancellation process, including any hearing, would enable EPA to protect the public health by removing potentially hazardous pes-

ticides from the market in a timely manner and would permit EPA to reserve suspension actions for those few situations that involve genuine imminent hazards.

2. Suspension.

H.R. 1627 would authorize the Administrator to issue an emergency suspension order prior to a proposed cancellation order provided the Administrator proceeds expeditiously to issue a proposed cancellation order. This would enable EPA to act promptly to suspend the registration of a pesticide that may pose an imminent hazard while assuring that a full risk/benefit evaluation of the pesticide is initiated within a reasonable time.

3. Implementation of NRC Report.

H.R. 1627 would require EPA, FDA and USDA to coordinate the development and implementation of procedures to ensure that pesticide tolerances adequately safeguard the health of infants and children, based on the conclusions and recommendations contained in the report entitled: "Pesticides in the Diets of Infants and Children" of the National Research Council of the National Academy of Sciences. These procedures would include collection of data on food consumption patterns of infants and children, improved surveillance of pesticide residues and increased sampling of foods most likely consumed by children, and toxicity testing procedures and methods of risk assessment that take into account unique characteristics of infants and children.

NFPA strongly supports these provisions, which would ensure adequate consideration of the safety of infants and children without unduly restricting EPA's scientific judgment.

4. Negligible Risk Standard.

Under current law, there are two different legal standards for pesticide residues in food. Tolerances for pesticide residues in raw agricultural commodities are issued under Section 408 of the FFDCA, which contains a general safety standard, no anticancer clause and requires consideration of benefits. Tolerances for pesticide residues that concentrate in, or are applied to, processed food are issued under Section 409 of the FFDCA, which contains the Delaney anti-cancer clause and does not expressly provide for consideration of benefits.

In 1987, the National Academy of Sciences (NAS), recommended that pesticide residues in raw and processed food should be regulated on the basis of a single negligible risk standard. Consistent with the NAS recommendation, H.R. 1627 would eliminate application of section 409 to pesticide residues in processed food and would provide that all pesticide residues in food are governed by the tolerance provisions of section 408.

H.R. 1627 would require EPA to set a tolerance at a level adequate to protect the public health taking into account, among other relevant factors, the validity, completeness and reliability of available data from studies of the pesticide chemical, the nature of any toxic effects caused by the chemical, available information and reasonable assumptions concerning the relationship of the data to human risk and to the dietary exposure levels of consumers (and major identifiable subgroups of food consumers, including infants and children).

A tolerance level for a pesticide residue in food would be deemed to be adequate to protect the public health if the dietary risk to consumers from exposure to the pesticide is negligible. This would implement the NAS recommendation for a uniform negligible risk standard for pesticide residues in food, would give EPA flexibility to ignore *de minimis* or insignificant risks and would permit the Agency to focus its limited resources on the highest risk pesticides.

The definition of "negligible risk" would not identify a specific level of risk that would be considered negligible or a numerical expression of that level, because science and the degree of knowledge and confidence in cancer risk assessment is constantly evolving and improving, and EPA needs to preserve the ability to keep pace with the developing science of risk assessment. The Administrator would be required, however, to set forth by regulation the factors and methods, including tests which are appropriate for the determination of dietary risk and most likely dietary exposure, for the determination of negligible dietary risk.

EPA would be required, where reliable data are available, to calculate dietary exposure on the basis of the percent of food actually treated with a pesticide and the actual residue levels of the pesticide that occur in food. This would help avoid exaggerated and unjustified exposure assumptions and would assist in developing more realistic risk projections.

5. Benefits.

H.R. 1627 would provide that EPA may establish a tolerance for a pesticide residue posing greater than a negligible risk if the agency determines that the risk is reasonable because (1) the risk to human health from loss of the pesticide outweighs the dietary risk attributable to the pesticide, (2) likely alternative pesticides or pest control methods pose greater risks to the public than the dietary risks attributable to the pesticide, or (3) loss of the pesticide would limit the availability of an adequate, wholesome and economical food supply, taking into account regional and national effects. This would assure that pesticide tolerance decisions are not made in isolation, that EPA fully considers all relevant factors and that a complete risk-benefit evaluation is conducted. In this manner, EPA will be able to set reasonable priorities and direct its limited resources against the most hazardous and least beneficial pesticides.

Food use pesticides provide important benefits for American agriculture. Loss of pesticides can cause reductions in crop yield and farm income, decreases in agricultural employment and harm to the international competitiveness of United States farmers who must compete with foreign producers who may continue to use pesticides that are banned in the United States. Pesticides also play an essential role in providing a wholesome, healthy, nutritious and affordable food supply. The Department of Health and Human Services (HHS), the Surgeon General, other government agencies, and prominent scientific and medical organizations have increasingly stressed the value of a nutritious diet, including ample amounts of fresh fruits and vegetables, in maintaining health and preventing disease. The loss of important food use pesticides can result in heightened risk of disease causing organisms in food, food price increases, adverse effects on food quality and reduction in the availability of nutritional food choices, particularly for low income consumers. In view of the important benefits of food use pesticides, we believe that it is essential that EPA be permitted to retain the authority to balance benefits against risks in pesticide tolerance decisions, especially since the Agency's risk estimates are based on multiple conservative assumptions and extrapolations.

6. Flow-through Provision.

NFPA strongly supports the provision of H.R. 1627 that would retain the flowthrough provision of current law. As under current law, H.R. 1627 would provide that if a tolerance or exemption is in effect for a pesticide chemical in a raw agricultural commodity, a residue of the chemical in a processed food made from the raw agricultural commodity shall not be considered unsafe as long as the concentration of the residue in the processed food when ready for consumption is not greater than the tolerance prescribed for the raw agricultural commodity. This provision avoids the necessity of establishing separate tolerances for pesticide residues in processed food and provides recognition of the fact that, in the vast majority of cases, pesticide residues are reduced and do not concentrate in processed food.

7. Pipeline Provision.

H.R. 1627 would provide that, where a tolerance or exemption for a pesticide chemical has been revoked, suspended or modified, a food that was legally treated with the pesticide shall not be deemed unsafe as long as the pesticide residue does not exceed the previously authorized tolerance level. EPA would retain the power to declare legally treated food unlawful, but only on the basis of a determination that consumption of the legally treated food during the period of its likely availability in commerce would pose an unreasonable dietary risk.

This provision would protect against unnecessary destruction of legally treated food, would prevent massive economic loss and marketplace disruption, and would assure that food producers are not unfairly penalized for use of legal pesticides that are subject to unpredictable regulatory action at a subsequent date.

Where a pesticide is identified as a potential carcinogen or other chronic hazard, applicable registrations and tolerances may be canceled on the basis of a risk calculation assuming lifetime exposure. Because food legally treated with such a pesticide would be available in the marketplace for only a relatively short period (i.e., one to three years), EPA would be authorized to take action against existing stocks only where it determined that exposure during the remaining period of market availability posed an unreasonable risk to consumers.

8. Metabolites and Degradation Products.

H.R. 1627 would codify EPA's existing policy with respect to pesticide metabolites and degradation products in food. Under that policy, quantities of a metabolite or degradation product in a food are considered 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 a different or greater health risk, the combined level of the metabolite or degradation product and the precursor chemical is above the tolerance for the precursor chemical, or the tolerance specifically excludes the metabolite or degradation product. This policy avoids 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.

9. International Harmonization.

With increasing international trade in food products, and U.S. government efforts to reduce trade barriers, it is important that meaningful steps be taken to promote international harmonization of pesticide tolerances. Consistent with this goal, H.R. 1627 includes a provision requiring EPA to take into account, and justify any departure from, recommended international pesticide maximum residue levels issued by Codex.

10. National Uniformity.

Under current law, states and localities may set tolerances for pesticide residues in foods that are lower than those established by EPA, or require warnings for food products containing pesticide residues that are legal under Federal law. In recent years, a number of states have set lower tolerances for certain pesticides, creating significant burdens on interstate commerce. H.R. 1627 would provide for national uniformity of tolerances for pesticides registerod or reregistered under the comprehensive safety data requirements adopted by EPA in 1985. This provision would secure EPA leadership in pesticide safety decisions, and would avoid the consumer confusion and substantial burdens on interstate commerce caused by special state tolerance requirements. Consumer protection would be assured by limiting required uniformity to pesticide tolerances supported by full scientific testing and recent EPA evaluation.

Under H.R. 1627 any state or local standard applicable to the same pesticide chemical for which a federal tolerance has been established would be required to be identical to the federal standard. States and political subdivisions would be precluded from circumventing prescribed tolerance uniformity through imposition of warning requirements or other indirect sanctions that would prohibit or penalize the production or sale of food because it contains pesticide residues in excess of a tolerance established by EPA.

States would be authorized to petition EPA for an exemption from a uniform federal tolerance where the state could establish adequate justification. Exemptions would be authorized only where EPA concluded, after notice and opportunity for public participation, that a special state tolerance is justified by compelling local conditions, such as unusual food consumption patterns, would not unduly burden interstate commerce, and would not cause any food to be in violation of Federal law.

It would be counterproductive for Congress to pass legislation establishing a negligible risk standard for pesticide tolerances in food while leaving any state that disagreed with the Federal policy free to impose a more restrictive standard. A state should not be permitted to impose severe burdens on interstate commerce through application of zero risk standard for pesticides where the Federal government has explicitly disavowed such a standard and there are no compelling reasons for the state to have a different standard.

In conclusion, NFPA commends the Subcommittee for opening a dialogue on reforming our nation's pesticide laws. We strongly believe that H.R. 1627 offers a balanced and focused reform package that will not only give EPA the tools necessary to reach reasonable and scientifically defensible tolerance decisions but also will ensure strong protections for public health and the environment, and we applaud the Subcommittee for its prompt action on this important issue.

Mr. BILIRAKIS. Thank you so much.

Mr. Stolte.

STATEMENT OF DENNIS STOLTE

Mr. STOLTE. Thank you, Mr. Chairman.

My name is Dennis Stolte. I'm senior director of governmental relations for the American Farm Bureau, the Nation's largest organization of farmers and ranchers.

The Farm Bureau enthusiastically supports H.R. 1627. Without this important legislation, farmers in virtually every State will lose

essential crop protection tools which may determine whether some farmers in some States can continue commercial production of crops.

The importance of this legislation is illustrated in the tables attached to my full statement. Table 1 lists each State and the crops in 45 States which will be affected by the court-mandated interpretation of cancellations we are talking about today. Table 2 gives more specific information on the percentage of crop acreages affected in selected States and I emphasize selected States; all States are not included.

For example, triadimefon is used on grapes in California to the extent of 216,000 grape acres. This product is used for treatment of powdery mildew. Strict interpretation of the Delaney Clause means that California grape growers no longer will be able to use triadimefon. In Virginia, growers of apples treat black rot with a product called thiophanate-methyl. One of the alternatives to thiophanate-methyl which will be canceled by Delaney is benlate. Benlate is also on the Delaney hit list.

There are other examples: 95 percent of Florida's cotton acreage is treated with acephate, a Delaney hit list product; 76 percent of the apples in Connecticut are treated with benomyl; 10,000 acres in New York; 85,000 acres of wheat in Arkansas is treated with mancozeb for disease control; 100 percent of the apples in Rhode Island are treated with propargite for mite control; and almost 18,000 acres of peanuts in the State of Virginia with iprodione for control of schlerodia mite.

Each of these examples when taken separately may seem unimportant, but taken collectively they seriously affect a large number of States and farms. The court consent decree means more cancellations and stricter regulation of inconsequential and insignificant safety risks unless Congress intervenes quickly to inject a dose of common sense into Federal pesticide policy.

A study which will be released by Auburn University here for this committee on June 19 has found that a 50 percent reduction in pesticide use which would be brought about partially by strict Delaney interpretation could also have some real major effects on consumers. The study has found that domestic consumption would decrease by 4 percent. Wholesale prices would increase by 17 percent. Retail prices would increase by 9 percent. The study concludes that, "The reduction in pesticide residues in fruits and vegetables which would result from a drastic reduction in pesticide use appears extremely small when compared to significant adverse economic effects on producers, adverse economic effects on consumers, and possibly adverse health effects on consumers." I would like to address an issue that Congressman Waxman raised in that the study had also found that one of the most important effects Delaney could have would be on low-income Americans who already consume 20 percent less fruits and vegetables than higher-income consumers. Delaney severely penalizes this group of poorer Americans in their efforts to improve their diet and health through greater consumption of fruits and vegetables.

The Delaney paradox has been addressed by previous speakers, but this is a very strong concern to the American Farm Bureau in that Delaney, through the paradox, discourages the registration of

newer, safer pesticide products. A second paradox of Delaney inhibits farmers in their real efforts to reduce pesticide use through integrated pest management. Integrated pest management incorporates biological controls, crop rotation, and cultural practices in an overall effort with use of pesticides to control pests. Without these important chemical controls, however, IPM can no longer be continued.

Mr. BILIRAKIS. Please summarize, Mr. Stolte.

Mr. STOLTE. Mr. Chairman, I will summarize.

It is important to note that while modern technology has greatly improved our ability to measure and detect the tiniest trace of chemicals in food, we have had no increase in our ability to make these numbers useful or meaningful in the food policy process. This does not mean that our current system is broken and in need of an overhaul. Rather, it suggests the need to carefully change pesticide policy to reflect scientific advancement. The Delaney Clause has not permitted us to evolve as necessary. Farmers can no longer wait for next week, next month, or next year for Delaney to be changed, it must happen in 1995 before court-mandated cancellations occur and are allowed to take effect.

Thank you very much.

[The prepared statement of Dennis Stolte follows:]

PREPARED STATEMENT OF DENNIS STOLTE, SENIOR DIRECTOR, GOVERNMENTAL RELATIONS, AMERICAN FARM BUREAU FEDERATION

Thank you Mr. Chairman. My name is Dennis Stolte. I am a Senior Director of Governmental Relations for the American Farm Bureau Federation, the nation's largest organization of farmers and ranchers.

Farm Bureau enthusiastically supports H.R. 1627. Without this important legislation, farmers in virtually every state may lose essential crop protection tools—products which may determine whether some farmers can continue commercial production of some crops.

The importance of H.R. 1627 is demonstrated in Tables 1 and 2 submitted with our written statement. Table 1 lists each state and the crops in 45 states which will be affected by a court mandated interpretation and enforcement of the Delaney Clause. Table 2 gives more specific information on the percentage of crop acreages affected in selected states.

BACKGROUND

In 1958, Congress passed a short amendment to the Federal Food, Drug and Cosmetic Act (FFDCA) known as the Delaney Clause. The clause begins with:

> "No additive shall be deemed safe if it is found to induce cancer when ingested by man or animal..."

The goal of the Delaney Clause is admirable—to prevent cancer-causing agents from entering our food supply. No one argued with that goal then and no one would argue the merits of that goal today. Incredible improvements in scientific method, knowledge and technology has since rendered the Delaney Clause obsolete. The science on which the Delaney Clause was based upen then—the best available science—is no longer the best available science today. Strict enforcement of Delaney's unreasonable zero tolerance standard will force the loss of crop protection products merely because they are detectable, not because they are unsafe.

H.R. 1627 provides something American farmers drastically need: a health-based standard that reflects current practice and which allows regulators to acknowledge improvements in residue detection and our understanding of the complex systems which govern health and food safety.

Much has happened since 1958 which make it important to push for reform of the Delaney Clause. There was no Environmental Protection Agency (EPA) in 1958. FIFRA, the Federal Insecticide, Fungicide and Rodenticide Act, was first passed by Congress in 1947. Unlike the Delaney Clause, FIFRA has changed and evolved in

tandem with science and public policy. FIFRA was most recently changed in 1988 and will, we hope, be changed again with H.R. 1627.

Our understanding of cancer has changed too, and we now know the important role that fruits and vegetables play in health and in lowering cancer risk. America's eating habits have changed over the years as newer farming techniques utilizing crop protection products have made fruits and vegetables abundant, affordable and available year-round. Since 1971, our per capita consumption of vegetables has risen 17 percent to 413 pounds. Per capita consumption of fruit has risen 23 percent to 278 pounds.[1] Americans are eating healthier and living longer as a result.

Agricultural technology has changed significantly since Delaney was enacted. Today, farmers are farming by the inch using satellite technology and global positioning systems. We control pests using a wide variety of new techniques including biological control, pheromones, genetic resistance, electrostatic sprayers, vacuums and many other new and exciting pest control methods. In 1958, these methods were not available. In 1958, there were no self-propelled combines. Today, they dot the land. Farmers are using radar to gauge true ground speed, lasers to level the land, on-board computers, and many other technological advances. Thirty-seven years ago, these new techniques were not even concepts. No one then could possibly envision the changes that would take place 37 years later, no more than we can predict what agriculture will look like in the year 2032.

This returns us to a central question: What was the intent of Congress in 1958? Clearly the intent was not to shackle us to 1950's technology in perpetuity. While their intent may not be clear, the result 37 years later is clear as defined by the recent court decision in *California* v. *Browner*. In this regard, Delaney can be characterized as an amendment of unintended consequences. While Congress may have acted with good intentions in 1958, they surely could not have anticipated how an obscure amendment might be played out in 1995.

For example, triadimefon (bayleton) use on grapes is one of the pesticides and crops affected by the recent court decision. California treats 216,000 grape acres with triadimefon for control of powdery mildew.[2] Strict interpretation of Delaney means that California grape growers can not use triadimefon. Farmers can control powdery mildew by applying just 2 ounces of triadimefon per acre. The alternative to triadimefon is sulfur. Farmers must apply 6 pounds of sulfur per acre to get the same level of control as using 2 ounces of triadimefon. Strict interpretation of the Delaney Clause means increased pesticide use on grapes in California, the nation's number one grape growing state.

Apple growers in Virginia use thiophanate-methyl for control of apple scab, bitter rot, flyspeck, powdery mildew, sooty blotch and black rot. Over half of the apple acreage in Virginia is treated with thiophanate-methyl. One of the alternatives to thiophanate-methyl is benlate. Benlate is also on the Delaney list and cancellation of both will eliminate grower's ability to manage resistance and reduce pesticide use.

There are other examples of *California* v. *Browner* cancellations that will affect farmers throughout the United States. Here are just a few of the crops that will be affected by Delaney cancellations:

- 95% of Florida's cotton acreage is treated with acephate. 290,000 acres of cotton in Arizona and 330,000 acres of cotton on Louisiana are treated with acephate.
- 76% of the apples in Connecticut are treated with benomyl. 10,400 acres of apples are treated in New York with benomyl.
- 85,000 acres of wheat in Arkansas is treated with mancozeb for disease control.
- 100% of the apples acres in Rhode Island are treated with propargite for mite control.
- Almost 18,000 peanut acres in Virginia are treated with iprodione for control of sclerotinia blight. Just over half of the grape acres in Oregon are treated with iprodione for control of bunch rot. For some crops and pests, there may be alternative controls. For others, there will not.

Each of these examples when taken separately may seem unimportant, but taken collectively seriously affect a large number of states and farms. And the court consent decree means more cancellations and stricter regulation of inconsequential and insignificant food safety risks unless Congress intervenes quickly to inject a dose of common sense into federal pesticide policy.

There are consumer impacts as well from strictly applying the Delaney Clause. In early June, Auburn University will finish a research project designed to examine the consumer impacts from policies that reduce pesticide use on fruits and vegeta-

[1] Economic Research Service, USDA.

[2] National Center for Food and Agricultural Policy, Pesticide Use in U.S. Crop Production. Also see Table 2.

bles.[3] According to the study, the following impacts represent the effects of a 50 percent reduction in pesticide use:

- Domestic production would decrease by 6 percent;
- Exports would decrease by 10 percent;
- Imports would increase by 3 percent;
- Domestic consumption would decrease by 4 percent;
- Wholesale prices would increase by 17 percent; and
- Retail prices would increase by 9 percent.

From a food safety standpoint, the study further concludes that:

> "...the roduction in pesticide residues in fruit and vegetables which would result from a drastic roduction in pesticide use appears extremely small compared to significant adverse economic effects on producers, adverse economic effects on consumers, and possibly adverse health effects on consumers."

Perhaps most important are the effects Delaney will have on low income Americans, consumers who already consume 20 percent less fresh fruits and vegetables than higher income consumers.[4] Delaney severely penalizes this group of Americans in their efforts to improve their diet and health through greater consumption of fruits and vegetables.

FARM BUREAU'S GOALS

In terms of the broader legislative package embodied in H.R. 1627, Farm Bureau is supportive of the following two goals. First, is the need to resolve the differences between FIFRA and the FFDCA as they relate to pesticide registration and the tolerance-setting process. These provisions would align pesticide regulation with recommendations made in the 1987 National Academy of Sciences (NAS) report, "Regulating Pesticides in Food: The Delaney Paradox." The "Delaney Paradox," as described in the NAS report, stems from the contradictory regulation in the risk/no benefit Delaney Clause vs. the risk/benefit standard in FIFRA. 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. Coordinating efforts in FIFRA and FFDCA is an essential component for pesticide reform.

H.R. 1627 resolves this problem by replacing the Delaney Clause with a single, negligible risk standard for pesticide residues in both fresh and processed foods. This single standard will give the EPA the flexibility it needs to accommodate future developments in science.

Our second goal is the need to consider a pesticide's benefits in the registration and tolerance-setting process. The most compelling reason of the benefits from pesticide use are described by Nobel laureate Norman Borlaug:

> "...if 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 U.S. or 60 percent of the American forests and woodland areas to cropland. Even this may be an underestimation, since the pasture and forest lands 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.

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 pesticides. Research from Texas A&M University entitled "The Economic Impacts of Reduced Pesticide Use on Fruits and Vegetables"[5] catalogs the benefits derived from pesticide use. These benefits include:

- Pesticides reduce the risks of crop failure and stabilize food production.

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[3] C. Robert Taylor, "Economic Impacts and Environmental and Food Safety Tradeoffs of Pesticide Use Reduction on Fruits and Vegetables."

[4] 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.

[5] 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.

- Pesticides increase yields and 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 reduces the amount of water needed for irrigation.
- Pesticides prevent soil erosion resulting from increased cultivation to control weeds.
- Pesticides 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.
- Pesticides allow food to be grown domestically, rather than depending on imports where we have little or no control over food production methods.
- Pesticides 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 poor quality foods if they are typically stored for long periods, like apples. High quality foods are essential for meeting export standards as well. Customer countries will reject U.S. products if they do not meet quality or phytosanitary standards.
- Pesticides decrease farm labor requirements. History has shown that it is difficult to attract labor to agriculture due to the often difficult working conditions.

FARM BUREAU POLICY FOR REDUCING PESTICIDE USE

In the seven years since Congress last passed amendments to FIFRA, the critics of pesticide use have opposed reforming Delaney and have advocated tighter controls and regulatory activity as the primary avenue for improving food safety and for achieving further reductions in pesticide use.

According to National Agricultural Statistics Service surveys and EPA sales figures, total pesticide use has trended downward since 1986. Not one of agriculture's critics has given anything more than lip service towards meaningful and effective measures that will further decrease pesticide use, outside of stricter regulation and maintaining the Delaney Clause.

Farm Bureau's message and goals have remained constant and clear during these years. 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.

Already much is being done. Last April, at the National Symposium for Integrated Pest Management (IPM), over 200 research projects highlighted the vast array of new ideas that will help farmers reduce total pesticide use. Our goal is to build upon the vast and impressive research network anchored through the land-grant university system and create new farming techniques that reduce pesticide use.

Farm Bureau policy for reducing pesticide use supports:

1. The widespread promotion and use of IPM as a method of reducing costs, risks, liability and total dependence on farm chemicals.
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 non-biological pesticides.
4. A beneficial insects category in USDA's competitive grants program.
5. Expanded educational programs to encourage the widespread adoption of IPM and the addition of IPM instruction as part of pesticide applicator training programs.
6. Improved training programs on the proper handling and safe use of pesticides to ensure the safety of handlers, applicators and agricultural workers.
7. The national effort of the IR-4 program for which we have urged Congress numerous times to appropriate needed funds.

Congress and EPA can also create incentives for farmers to reduce pesticide use and to find safer alternatives. Incentives should include:

- Streamlining the EPA registration process for newer, safer products. The current registration process is long and expensive and is a disincentive to bring new

products on the market. Safer products should have an easier and faster registration path. EPA has recently initiated a program to expedite this process, which we believe is appropriate and commendable.

- EPA should deregulate non-chemical controls and pesticide products generally regarded as safe (GRAS).
- EPA should work to harmonize federal/international registration efforts and grant registrations to international products that meet U.S. standards.

CONCLUSION

There is a lot of good news for the American food consumer: the supply of food is bountiful, quality is unparalleled, variety is ever-expanding and prices are reasonable. The American farmer/government/university food production system is unrivaled—our quality of life and health provide 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. This does not mean that our current system is broken and in need of an overhaul. Rather, it suggests the need to carefully change pesticide policy to reflect scientific advancement. The Delaney Clause has not permitted us to evolve, as necessary.

Farmers can no longer wait for next week, next month or next year for Delaney and minor use pesticide reform. It must happen in 1995 before court mandated cancellations occur and are allowed to take effect.

We strongly urge your favorable consideration of H.R. 1627.

Thank you for the opportunity to comment.

Table 1—States and Crops Affected by Delaney Clause Cancellations

State	Crops Affected
Alabama	Cotton, Soybeans, Tomatoes, Wheat.
Arizona	Cotton, Citrus, Grapes.
Arkansas	Cotton, Apples, Grapes, Rice, Wheat.
California	Cotton, Apples, Grapes, Citrus.
Colorado	Apples, Tomatoes, Grapes.
Connecticut	Apples, Tomatoes.
Delaware	Apples.
Florida	Cotton, Citrus, Tomatoes, Soybeans, Wheat, Sugarcane.
Georgia	Cotton, Apples, Tomatoes, Grapes, Soybeans, Wheat.
Hawaii	Pineapple, Sugarcane.
Idaho	Apples.
Illinois	Apples, Tomatoes, Wheat.
Indiana	Apples, Tomatoes, Wheat.
Iowa	Apples, Tomatoes.
Kansas	Apples, Grapes.
Kentucky	Apples, Tomatoes, Wheat.
Louisiana	Cotton, Rice, Soybeans, Wheat, Sugarcane.
Maine	Apples.
Maryland	Apples, Tomatoes.
Massachusetts	Apples, Tomatoes.
Michigan	Apples, Grapes, Tomatoes, Wheat.
Minnesota	Apples.
Mississippi	Cotton, Soybeans, Rice, Wheat.
Missouri	Cotton, Apples, Grapes, Rice, Tomatoes, Wheat.
Nebraska	Barley, Oats.
New Hampshire	Apples.
New Jersey	Apples, Tomatoes, Grapes, Wheat.
New Mexico	Cotton.
New York	Apples, Grapes, Tomatoes, Wheat.
North Carolina	Cotton, Apples, Grapes, Soybeans, Wheat, Peanuts.
North Dakota	Soybeans, Barley, Wheat.
Ohio	Apples, Grapes, Tomatoes, Wheat.
Oklahoma	Cotton, Apples.
Oregon	Apples, Grapes.
Pennsylvania	Apples, Grapes, Tomatoes, Wheat.
Rhode Island	Apples.

Table 1—States and Crops Affected by Delaney Clause Cancellations—Continued

State	Crops Affected
South Carolina	Cotton, Apples, Grapes, Soybeans, Wheat.
Tennessee	Cotton, Apples, Tomatoes, Soybeans, Wheat.
Texas	Cotton, Rice, Tomatoes, Grapes, Wheat.
Utah	Apples.
Vermont	Apples.
Virginia	Apples, Grapes, Tomatoes, Wheat, Peanuts.
Washington	Apples, Grapes.
West Virginia	Apples, Wheat.
Wisconsin	Apples, Tomatoes.

SOURCE: National Center for Food and Agricultural Policy, "Pesticide Use in U.S. Crop Production." AFBF Public Policy Division

Table 2—Affected States and Number and Percent Acres Treated by State as a Result of Delaney Cancellations—Selected States

Chemical	Crop	State	% Acres Treated	Acres Treated	Lbs
Acephate	Cotton	FL	95%	47,025	
		AZ	69	293,250	
		AL	40	163,200	
		NC	40	150,800	
		LA	38	330,600	
		MS	18	242,172	
		CA	7	77,350	
		TX	4	143,400	
	Soybeans	MS	4	70,000	
		AL	4	10,800	
Benomyl	Apples	CT	76	2,919	
		GA	44	1,188	
		MD	40	1,721	
		DE	40	412	
		WI	36	2,556	
		OH	28	2,660	
		NY	20	10,400	
		CA	14	4,452	
	Citrus	FL	5	29,180	
	Grapes	MO	62	713	
		VA	37	543	
		NC	37	192	
		CA	9	59,004	
		WA	7	2,170	
	Rice	AR	28	386,400	
		LA	14	86,800	
		TX	14	49,140	
		MS	5	13,750	
	Tomatoes	VA	100	3,400	
		PA	90	4,950	
		CT	65	244	
		IL	30	748	
		FL	18	9,270	
Captan	Grapes	MO	100	1,150	
		NC	88	458	
		VA	88	1,292	
		OH	23	460	
		NY	16	5,280	
		CA	8	54,488	
Thiodicarb	Cotton	AL	70	285,600	
		FL	65	32,175	
		LA	43	374,100	
		MS	38	511,252	
		AZ	19	80,750	
Dimethipin	Cotton	MS	23	309,442	

—Affected States and Number and Percent Acres Treated by State as a Result of Delaney Clause Cancellations—Selected States—Continued

Chemical	Crop	State	% Acres Treated	Acres Treated	Lbs AI Applied
		LA	15	130,500	35,235
		FL	10	4,950	1,336
		MO	10	32,800	9,840
		NC	10	37,700	11,687
		AR	5	80,750	19,600
rbe	Citrus	AZ	51	18,870	33,777
		CA	34	83,878	141,334
		FL	1	5,836	7,295
eb	Barley	ND	1	26,500	26,500
		NE	1	300	480
	Oats	NE	1	2,200	2,200
	Wheat	MS	12	30,000	48,000
		NY	12	13,200	26,400
		AR	10	85,000	136,000
		TN	9	25,200	40,320
		VA	7	18,550	29,680
		ND	1	114,200	182,720
razon	Citrus	FL	20	116,720	441,202
		CA	5	12,335	17,799
		TX	5	550	794
		AZ	5	1,850	2,670
rifen	Cotton	MS	12	161,448	24,217
		LA	12	104,400	15,660
		CA	9	99,450	24,266
		AZ	9	38,250	9,333
		FL	5	2,475	371
	Mint	OR	27	13,365	3,609
		WA	27	9,342	2,522
		ID	10	1,780	1,406
pte	Apples	RI	100	623	997
		UT	90	4,641	6,489
		CT	68	2,612	6,489
		NH	62	2,290	3,458
		NJ	57	2,508	5,944
		NY	57	29,640	70,247
		MI	47	25,145	61,354
		IL	47	4,091	9,983
		WA	7	11,200	26,544
	Citrus	FL	6	35,016	71,783
		CA	2	4,934	11,817
	Grapes	CA	39	255,684	406,538
nate-methyl	Apples	PA	62	14,880	10,267
		MO	60	3,535	742
		SC	58	2,088	2,861
		VA	53	10,494	10,284
		ME	51	3,719	2,008
		NH	51	1,884	1,017
		VT	51	2,411	1,302
		NY	40	20,800	18,304
		CA	16	5,088	5,281
hion	Apples	SC	31	1,116	201

Table 2—Affected States and Number and Percent Acres Treated by State as a Result of Delaney Clause Cancellations—Selected States—Continued

Chemical	Crop	State	% Acres Treated	Acres Treated	Lbs AI Applied
		WA	22	35,200	5,632
		OR	20	1,980	317
		MI	19	10,165	2,033
		IA	19	473	95
		IN	19	1,131	226
		IL	19	1,654	331
		CA	16	5,088	687
	Grapes	TX	90	3,511	386
		MI	76	8,360	1,588
		AZ	75	3,375	1,215
		MO	72	828	166
		NC	70	364	44
		NY	67	22,110	4,422
		WA	40	12,400	3,596
		CA	33	216,348	33,318
	Wheat	MS	22	55,000	5,500
		LA	22	37,400	3,740
		GA	18	63,000	6,300
		AL	18	17,100	1,710
		AR	10	85,000	8,500
		VA	10	26,500	3,445
		TX	1	38,000	3,800
Iprodione	Grapes	WA	51	15,810	24,031
		OR	51	2,142	3,256
		VA	34	499	1,203
		NC	34	177	426
		SC	34	92	221
		AR	32	704	704
		CA	15	98,340	68,641
	Peanuts	NC	19	29,070	11,628
		VA	19	17,670	7,068
	Rice	AR	12	165,600	87,768
		MS	12	33,000	17,490
		MO	8	8,960	8,960
		LA	6	37,200	19,716
		TX	6	21,060	11,162

SOURCE: National Center for Food and Agricultural Policy, "Pesticide Use in U.S. Crop Production." AFBF Public Policy Division

Mr. BILIRAKIS. Thank you so much, sir.

Dr. Ziller.

STATEMENT OF STEVEN ZILLER

Mr. ZILLER. Thank you, Mr. Chairman.

I'm Steve Ziller, vice president of scientific and technical affairs at the Grocery Manufacturers of America. Our association represents companies which manufacture approximately 85 percent of the grocery products in the United States, and their members' annual sales exceed $360 billion.

GMA strongly supports H.R. 1627, the Food Quality and Protection Act of 1995, which was recently introduced by Chairman Bliley and Chairman Roberts as well as more than 50 other original cosponsors, and I would also note that a majority of this committee has cosponsored that legislation.

For almost two decades GMA has supported the concept of revising the statutory provisions governing Federal regulations of pes-

icides used in the production of food. This bill represents a marked mprovement over a number of proposals for the regulation of food ıse pesticides introduced in Congress during the last decade.

Changes in science and technology since the 1950's made it enirely appropriate to review and revise the current statute to enıure continuation of a high standard of safety and also to make the ›rocess of establishing residue tolerances more efficient and effecive.

Furthermore, the 1992 *Les* v. *Reilly* decision and the California versus Browner settlement have complicated EPA's task of applying the statute in a rational and scientifically defensible fashion. A whole range of pesticides are expected to be canceled in the next few years as a result of these court decisions.

The bill before this committee would make a much needed change in the Act by establishing a negligible risk standard for pesticide residues in both processed and unprocessed foods. The National Academy of Sciences recommended such a change in 1987 in a report on this subject.

Because these and other proposed revisions of current law would appropriately modernize regulation of food use pesticides, GMA endorses H.R. 1627. I would just like to briefly summarize some of the key provisions of the legislation.

Negligible risk standard. This certainly is a modification of current law. The standard in this bill was recommended by the NAS and has been discussed by a number of people today. I certainly think that the NAS report on children's exposure to pesticide residues would allow EPA—in fact, mandate EPA to incorporate their recommendations for children and other sensitive subpopulation groups. Equally important, the current bill retains the long-standing practice of considering health, nutrition, and other consumer benefits, including the impact of the loss of the pesticide on the availability of an adequate wholesome and economical food supply when determining whether a tolerance should be permitted for a pesticide in food.

This bill also properly retains the provision that raw commodity residues appearing in processed foods are lawful so long as these residues have been removed, to the extent possible, with good manufacturing practices and the concentration of such residues in the ready-to-eat form of the food does not exceed the raw product tolerance.

GMA applauds the provision of the bill that precludes States from issuing different tolerances, warning label requirements, or other limitations on residues in food products of pesticides registered or reregistered after April 25, 1985. Once a Federal pesticide residue tolerance is scientifically established, that determination should apply uniformly across the States and local governments with rare exception.

In sum, Mr. Chairman, GMA supports H.R. 1627. This bill represents a balanced response to recent difficulties encountered in EPA tolerance setting activities. Under the proposed legislation, regulatory decisions will better reflect contemporary scientific information about the risks and benefits of pesticide use in food production.

Thank you.

[The prepared statement of Steven Ziller follows:]

PREPARED STATEMENT OF DR. STEVEN ZILLER, VICE PRESIDENT FOR SCIENCE AND TECHNICAL AFFAIRS, GROCERY MANUFACTURERS OF AMERICA

Good morning. I am Dr. Steven Ziller, Vice President for Science and Technical Affairs, for the Grocery Manufacturers of America, Inc. GMA is the national trade association representing companies, which manufacture and market branded grocery products, comprising the largest volume (85 percent) of the food and grocery items sold in the U.S. Member company annual sales exceed $360 billion. GMA supports H.R. 1627, the "Food Quality Protection Act of 1995," which was recently introduced by Chairman Bliley and Chairman Roberts, as well as more than 50 other original cosponsors. This legislation has also been introduced in the last two Congresses.

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. With that, we applaud the efforts of the sponsors of H.R. 1627. This bill represents a marked improvement over a number of proposals for the regulation of food-use pesticides introduced in Congress during the last decade. GMA supports passage of this legislation.

Changes in science and technology since the 1950s make it entirely appropriate to review and revise the current statute to ensure continuation of a high standard of safety, and also to make the process of establishing residue tolerances more efficient and effective. Many of the advances in analytical chemistry and the science of quantitative risk assessment could not have been foreseen several decades ago.

Furthermore, the 1992 *Les* vs. *Reilly* decision by the U.S. Ninth Circuit Court of Appeals, which turned back the Environmental Protection Agency's policy of disregarding de minimis risks under the Delaney Clause, and the more recent *Cal* vs. *Browner* settlement accepted by the U.S. District Court for the Eastern District of California have complicated EPAs task of applying the statute in a rational and scientifically-defensible fashion. A whole range of pesticides are expected to be canceled in the next few years, as a result of these court decisions.

The bill before this subcommittee would make a much needed change in the Act by establishing a negligible risk standard for pesticide residues in both processed and unprocessed foods. The National Academy of Sciences recommended such a change in a 1987 report on the subject. Because these and the other proposed revisions of current law would appropriately modernize regulation of food-use pesticides, GMA endorses H.R. 1627. We would like to add the following comments on specific elements of the bill.

DISCUSSION

Negligible Risk Standard

As previously mentioned, the proposal would adopt a negligible risk standard as the basis for establishing safe pesticide residue levels in food, a modification of current law recommended by NAS. The bill specifically addresses the concerns expressed in the recent NAS report on children's exposure to pesticide residues by mandating that EPA consider these and other sensitive population groups.

The sponsors of the bill have correctly recognized that the same safety standard should apply in setting tolerances for both raw commodities and processed foods. Moreover, the standard is formulated in such a way as to allow for the consideration of new scientific knowledge and innovations in production techniques, unlike other proposals that had sought to replace the Delaney Clause with equally rigid and unscientific criteria for evaluating safety.

Equally important, the current bill retains the longstanding practice of considering the health, nutrition, and other consumer benefits—including the impact of the loss of a pesticide on the availability of an adequate, wholesome and economical food supply—when determining whether a tolerance should be permitted for a pesticide in food products. Pesticides are highly important to the production of food in this country. These chemicals indirectly promote public health by controlling disease and damage to food, and thereby providing nutritious and low-cost products for American consumers. The NAS recognized that the benefits of pesticide users are an important consideration in tolerance decisions. Under the negligible risk standard set forth in the bill, EPA will be able to focus its resources on the most important issues and not waste valuable resources on insignificant or negligible ones.

Tolerances for Processed Foods

GMA agrees that both processed and unprocessed foods should be subject to the same negligible risk standard. Separate tolerances for raw and processed commodities are not necessary. Section 402(a)(2) of the existing statute (sometimes referred to as the "flow through provision") provides that raw commodity residues appearing in processed foods are lawful so long as these residues have been removed to the extent possible with good manufacturing practices and the concentration of such residues in the ready to eat form of the food does not exceed the raw product tolerance. The flow through provision recognizes that pesticide residues normally decrease during processing, and H.R. 1627 properly retains this provision.

Measurements of Dietary Exposure

Actual levels in raw agricultural commodities and processed foods are substantially below the tolerances that have been established for raw products under section 408 of the Act. This occurs because EPA exposure calculations are based on unduly conservative assumptions about pesticide use and the extent to which processing reduces any remaining residues. Application of pesticides to food crops is performed to minimize residues at time of harvest, and post-harvest processing generally reduces those residues even further. Under the bill, the agency would calculate dietary exposure levels on the basis of actual data whenever possible.

Food Products in the Pipeline

In the event that a tolerance is revoked, foods from crops lawfully treated with the affected food-use pesticide should not unnecessarily be subject to seizure and destruction. Unless EPA determines that consumption of a legally treated food would pose an unacceptable risk during the depletion of existing stocks, there is no justification for the serious marketplace disruptions and economic losses that would apply that decision against products "in the pipeline." The bill correctly exempts such food products.

National Uniformity

GMA applauds the provision of the bill precluding states from issuing different tolerances, warning label requirements, or other limitations on residues in food products of pesticides registered or reregistered after April 25, 1985. Once a federal pesticide residue tolerance is established, that determination should apply uniformly. Otherwise, differing state standards, whether they are imposed directly through tolerances or indirectly through labeling requirements, will significantly burden interstate commerce. In the unlikely event that special local conditions necessitate variances from the uniform federal standard, states could petition EPA.

Streamlined FIFRA Cancellation Procedures

GMA supports the procedural revisions of FIFRA which allow expedited suspension and cancellation of pesticides when warranted, as well as the requirement that existing residue tolerances be reviewed in conjunction with the review of pesticide registrations under FIFRA. Eliminating dangerous agricultural chemicals in an expedited fashion would serve to better safeguard public health and maintain continued consumer confidence in the safety of the food supply.

Conclusion

In sum, Mr. Chairman, GMA supports H.R. 1627. This bill represents a balanced response to recent difficulties encountered in EPA tolerance-setting activities. Under the proposed legislation, regulatory decisions will better reflect contemporary scientific information about the risks and benefits of pesticide use in food preduction.

Mr. BILIRAKIS. Thank you very much, Dr. Ziller.

I'll change the process very briefly at this point and recognize my colleague from New York, Mr. Towns, for his questioning.

Mr. TOWNS. Thank you very much, Mr. Chairman. I will try not to use up the 5 minutes. I appreciate the special consideration.

Let me just ask all of you this one question. If Delaney reform is not enacted this year, what would be the impact on companies and agricultural interests that all of you represent? I would like a response from each of you.

Mr. STOLTE. For some farmers—I'm speaking for agricultural producers—I think there would be alternative pesticides for the ones that are scheduled to be revoked under Delaney; but for other

growers there would be no good substitutes for those pesticides, and in some cases we have strong information to indicate that commercial production of some crops would not take place. Farmers would either be forced to give up production of that crop or be forced to grow a different crop for which they had an effective crop protection tool.

Ms. DUGGAN. For the food processing industry, the vagaries of the marketplace and the vagaries that would be associated with the production of the crops would extend into processing those to the marketplace, and we would have a tremendous amount of work to do to ensure that we don't have illegal residues on any of the foods that we produce. There would be a huge amount of testing procedures that would have to be implemented in addition to simply the additional costs and the potential unavailability of certain commodities.

The responsibility for ensuring that a food is under tolerance is at the manufacturing level, and that entire program would have to be implemented to ensure that none of these 80 crop pesticide combinations, should they be canceled, were present on food products.

Mr. TOWNS. Thank you.

Mr. ZILLER. I would agree with that, and would also add the one additional factor which is very significant, which is, once these things get into play as far as EPA banning things, you get a tremendous reaction—overreaction, in the media which causes a tremendous problem for food manufacturers, their products, their brands, the confidence of the consumers, and so forth. I think it is a real serious thing. I would certainly hope that legislation could come forward to prevent that sort of banning.

Mr. TOWNS. Let me thank all three of you for your testimony.

Thank you, Mr. Chairman. I yield back.

Mr. BILIRAKIS. I thank the gentleman. His time has expired.

Mr. Whitfield.

Mr. WHITFIELD. I would like to ask Ms. Duggan a question.

I had earlier asked Dr. Goldman in the first panel about the petition of the food industry relating to concentration and coordination policy. I was just wondering if you would have any additional comments about the process that is going on there and what is your view as to why it is taking so long.

Ms. DUGGAN. Well, yes, I would love to answer that question. Thank you.

The National Food Processors Association petition that was submitted in September 1992, almost 3 years ago, made the case that we think EPA has been misreading the statute for many, many years in the way it has regulated pesticides. It argues that Congress never envisioned pesticide residues to be treated as food additives, something that was added directly to the food supply, and never envisioned that they would need a food additive tolerance, that the raw commodity tolerance should have sufficed to make the processed food legal as long as the residues were under the raw product tolerance.

EPA, over the course of the years, as the science evolved and detection methods were improved, developed a theory that there was some potential exposure associated with concentration in the proc-

essed form, that if you, for instance—actually, I have a chart here that might help explain some of this, as you can see it.

For instance, if you took a tomato and turned it into tomato paste, the residue might concentrate, and not necessarily concentrating above the raw product tolerance but by virtue of concentration, would require then a food additive tolerance under section 409 where the Delaney Clause is present. So they began to require the concentration data, and in fact there was some data that some of these things do concentrate. They also began to evaluate foods on a processed level as opposed to the ready-to-eat form for consumers. So they would take the tomato paste and since it concentrates, the agency would require a 409 tolerance, not recognizing that nobody really eats tomato paste; they eat pizza sauce or they eat pizza that has been reconstituted, and therefore concentration may not actually ever been an issue for the consumer.

So we believe that concentration, No. 1, doesn't really have a scientific basis and that the flow-through provision should suffice to make all of these processed foods legal under Section 408. In addition to the concentration policy, when EPA chose to require a Section 409 tolerance on a processed form and if the Delaney Clause came into play, which it has with about 80 combinations of crops and chemicals, then they would cancel the 409 and the 408, thereby driving Delaney back into the system into the raw product commodities.

We have argued that concentration and coordination should be rescinded and that the flow-through provision and the ready-to-eat provision should be given new life. Virtually all of this potential crisis associated with this consent decree could be mitigated, and if you ever had a situation where the EPA really thought there was a food safety concern with a processed product, they could set that tolerance under a completely different section of the law, Section 406, where they have the ability to prohibit adulterated food. A tolerance could be set there, and there is no Delaney Clause in that part of the law.

So the NFPA petition with that legal framework was submitted 3 years ago, and EPA did not respond to it. In the meantime, a pall that has been cast over these combinations of chemicals and crops, and the marketplace is waiting, farmers are wondering whether or not if they treat their foods this year the processed form will be legal in the future, and the regulatory uncertainty is very, very great.

Mr. WHITFIELD. Is there anything in this legislation that would clear up the contradiction between sections 402 and 408 and 409?

Ms. DUGGAN. This legislation is actually a better alternative than trying to do this administratively, because as long as the Delaney Clause is in place you are going to have some difficulty in regulating. You will still have two separate standards for raw and processed foods. You will then also have a conflict with FIFRA. So this legislation would clear up all of these issues.

But our point is that EPA does have discretion right now to mitigate most of these problems and has not chosen to respond to the policy issues we raised. The consent decree that they agreed to on February 7, 1995 requires them to respond to the NFPA petition, and their original date was April 9. They went to court and got an

extension for June 9, which is this Friday, and of course we have no idea how they are going to respond on June 9.

But the interesting thing about the way the consent decree was written is that the plaintiff, Natural Resources Defense Council, can reopen the litigation and quash the consent decree if it disagrees with the policy issues established in their response to the petition, so there is almost a veto process there, and so EPA is between a rock and a hard place. Either the agency denies the NFPA petition and goes through the expedited schedule of reviewing and then canceling the Delaney tolerances or they grant the NFPA petition and try to mitigate this. In either case they will be taken to court. If they grant the NFPA petition they will be taken to court on one set of policies and one court case. If they don't grant the NFPA petition and they cancel all of these tolerances they will have litigation on every one of them extending for years into the future. So from a cost and a taxpayer standpoint we clearly think they should grant the NFPA petition.

But the best of all possible worlds is to pass this piece of legislation, and that would obviate this entire process. There would be regulatory certainty and you would have a science-based standard that governed all food for all health effects, and that is clearly preferable.

Mr. WHITFIELD. Thank you very much.

Mr. BURR [presiding]. The gentleman's time has expired.

Dr. Coburn.

Mr. COBURN. Thank you.

I want to get back to this concern that was raised over FIFRA preempting FDA. Address that for me, if you will, Ms. Duggan, and let's talk about that and if in fact that is a legitimate concern in this legislation and what can be done to change that.

Ms. DUGGAN. The issue that they have raised is possibly legitimate, but I think that we have the opportunity to work with the committee to resolve that issue. It is clearly not what the industry would want to see, and we did not read this language as requiring it.

I think the interest of the industry in supporting a provision to coordinate FIFRA and Food, Drug, and Cosmetic Act tolerance decisions more closely was to avoid situations where, if a chemical did not have a tolerance, it also did not have a registration so that it wouldn't be available in the marketplace and it wouldn't be used on farms and then that product would then not be adulterated. If this provision does not in fact accomplish that and create more regulatory problems than it solves then, we clearly have an interest in working with the committee to resolve that.

Mr. COBURN. And you think that can be done?

Ms. DUGGAN. Absolutely. No question.

Mr. COBURN. All right. Earlier it was mentioned that there was no response initially to your petition and therefore there was a forced response to the petition. Is that commonplace in—and I would like all three of you to answer this—in terms of your dealing with this Government? That has been my finding. I'm just wondering if it is the same as yours. I haven't taken anybody to court to get an answer to a letter yet, but I may.

Ms. DUGGAN. It is an all too common feature of regulatory practice to petition the Government for policy answers and policy questions and not to receive an answer.

Another issue that is under the jurisdiction of this subcommittee is the issue of FDA reform—matters over which there has been quite a bit of debate. In the food additive petition process, it takes an average of 7 years to get a decision on a food additive petition. In some cases—from the FDA—we have petitions that have been pending for several decades. So that is a hallmark, I guess, of dealing with the agencies.

Very, very recently NFPA petitioned the FDA on some health claims matters, asking for changes in the health claims regulations, and we received an answer within 2 weeks of the statutory deadline, which was 180 days, and I think that was a unique experience that we welcomed, and we praised the agency for being able to meet that deadline, but it was certainly the exception and not the rule.

Mr. COBURN. Dr. Goldman commented that there perhaps was one section of this bill that was too onerous in terms of requiring them to respond within 30 days. Would you care to comment on that? Is that an inappropriate amount of time for a government agency to respond to an inquiry?

Ms. DUGGAN. Was she referring to the FIFRA cancellation and suspension procedures?

Mr. COBURN. Yes.

Ms. DUGGAN. The administration's characterization of that provision, which is not under the jurisdiction of this committee, is curious to me. Right now the current procedure takes about 4 to 5 years to cancel registration under FIFRA. This piece of legislation would set a 1-year definitive time line for that procedure to take place, and the hearing would I believe be required within 20 days.

Whether you think that is an appropriate timeframe for streamlining or not, it is clear that that procedure will be much shorter and much cleaner than the current procedure which is a trial type hearing. So I think it is a question of degree about how short it should be and what the rights of the registrant should be and what the opportunities for scientific peer review ought to be. Clearly the industry has a certain viewpoint that due process and peer review should be strong features of a cancellation procedure.

Mr. COBURN. I agree.

Mr. STOLTE. I think in many cases it is in farmers' best interest to expedite the cancellation process as well because getting those older, more toxic products off the market encourages the development and the new market for newer, safer products, and we are interested in that.

Mr. COBURN. Okay.

Dr. Ziller.

Mr. ZILLER. I agree, and I go back to my earlier point which is, whenever you have uncertainty around these kinds of issues in the regulatory sphere you always have uncertainty in the minds of consumers, which is not good.

Mr. COBURN. Fine. Thank you.

I don't have any additional questions, Mr. Chairman.

Mr. BILIRAKIS. I thank you, Dr. Coburn.

Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman.

Mr. Stolte, just a follow-up on part of your testimony where you said that modern technology has greatly improved our ability to make sure or detect the tiniest trace of chemicals in food, yet current law, I think, doesn't allow us to use it. Could you expand on that just a little bit?

Mr. STOLTE. Well, we have had tremendous improvements, No. 1, in detection, in our ability to detect pesticide residues. As several people have stated, we have gone from parts per thousand or 10,000 to parts per billion or quadrillion, which is common these days. So we have the situation now where we are going to have broad-scale cancellation of pesticide uses not because they are not safe, but because they are detectable because of modern science, and we are saying that is wrong. If there is a safety concern those uses should not be allowed, but if they are canceled strictly because they are detectable that is not good regulatory policy.

I think the other area where we have made tremendous strides, and I don't have a medical background—but we have also made tremendous strides in determining cancer risks, cancer causes, real health concerns, as opposed to alleged health concerns since 1958, and Delaney simply hasn't allowed us to progress in those areas the way we need to.

Mr. BURR. Let me ask you, is it possible under current law that pesticides could be approved but products rejected because of the use of those pesticides? I thought I understood something that one of the three of you said earlier about that, that potential could exist under current law. Is that in fact true?

Ms. DUGGAN. If you have a situation where you have a pesticide that is registered but it has no tolerance and it is available in the marketplace, it is feasible that someone could use that chemical. Then the residue on the food that was produced from it would of course be illegal because there would be no tolerance for it. We don't expect that that happens very often, but we would like to make sure that those two things are coordinated, that if there is no tolerance, there is also no registration. But right now the illegal application or a misapplication of a pesticide could result in a residue that was either over tolerance or was somehow illegal, or the use of a product that is used on something for which it has no tolerance or for which it is not approved, and that would be an illegal application and would be adulterated under the meaning of the Food, Drug, and Cosmetic Act and could be seized. The person who made the application would be criminally prosecuted, which does happens.

Mr. BURR. And may not know that they have broken the law. Is that conceivable?

Ms. DUGGAN. It is possible.

Mr. STOLTE. Yes, it is.

A related problem that is with the use of so-called minor use pesticides. For instance, we have pesticide products that are registered for use on one type of lettuce, and there are about five different kinds of leafy lettuce. It is because of the registration costs for that product, and you are talking hundreds of thousands of dollars in some cases to register it for that particular use. It is registered for

use on one species of lettuce but not another. Technically, use of that product on a nonregistered type of lettuce is a violation of the label and punishable. That is another related problem we have to Delaney.

Ms. DUGGAN. I should add that that does not necessarily mean that there is a public health risk associated with that. It is simply that there is no registration.

Mr. STOLTE. That is right. It means the economic costs are not justified.

Mr. BURR. Dr. Ziller, just a comment from you about the EPA's flexibility under H.R. 1627, because I think that we had quite a few comments early on about the lack of flexibility, and, you know, my interpretation of this was that the decisions were sort of laid in their lap. Is that in fact what you read into H.R. 1627?

Mr. ZILLER. Right, I agree with you. My reading is that the bill gives a tremendous amount of scientific flexibility to EPA to develop the appropriate kinds of additional regulations that are involved in implementing the law, and that is the intent, I think. I think the hang-up is more the legal one—what do we do if we get sued? If you have gone through appropriate rulemaking procedure you should have something that will withstand a charge.

Mr. BURR. I found it a little odd—and you might want to comment on this—that Dr. Goldman did not want to see, I think, in response to Mr. Whitfield about why they negotiated the court settlement, that they didn't want to see the courts come in and regulate what they did yet she was sitting in front of Congress, if I interpreted her correctly, asking us to do the same. Was that your interpretation of it?

Mr. ZILLER. Yes.

Mr. BURR. My time has expired, Mr. Chairman. I yield back.

Mr. BILIRAKIS. I thank the gentleman.

I think I'm just going to concentrate on one question. EPA has stated that it is just as significant to be concerned about others in addition to infants and children. Mr. Waxman certainly has argued very, very strongly that H.R. 1627 does not provide sufficient measures to assure that pesticide tolerances safeguard infants and children, and that is important.

I don't know, Ms. Duggan, we all have children, we all have grandchildren, so we are concerned about this, and that is really why I tried to get to the point with the previous panel to see if they had any axes to grind because they made statements that they felt that H.R. 1627 is not in conflict with those safeguards. So I would like to hear your responses. Take as much time as you would like.

Ms. Duggan.

Ms. DUGGAN. The children's safety provisions are a new feature of the bill since the time it was introduced in the last Congress, and it is directly responsive to the National Academy of Sciences report on the diets of infants and children, and it seems to be designed to require the administration, the administrator of EPA, FDA, and USDA, to implement the recommendations of the report. Specifically, it requires them to collect appropriate data on consumption patterns of infants and children. It requires them to improve their surveillance of pesticide residues and collect information on what residues are in the marketplace so we will know what

the exposure is and to have better information about what the sensitivities are of infants and other subpopulations and what the toxicity effects are. Taken together, that information should dramatically improve risk assessments and should produce tolerances that are fully protective of children.

That is certainly what we recommend, and it is in fact what the NAS recommended we do. So I feel that this is a very good provision that is new to the bill this year and should be adopted by the Congress.

Mr. BILIRAKIS. Thank you.

Mr. Stolte.

Mr. STOLTE. Well, I can't embellish that too much.

I think the new provisions in the bill, along with the existing authority that the agency has brought up in previous testimony to protect infants and children and special populations—I think we have made an extra effort to safeguard the health of those subpopulations, and we feel the bill is very adequate.

Mr. BILIRAKIS. Dr. Ziller.

Mr. ZILLER. I just want to add one slightly different slant on this. You know, when we sit up here we really represent a lot of member companies that are very responsible food processing manufacturers throughout the United States, some of whom are worldwide companies, and they have a lot to lose if their products are not safe. When earlier drafts of this legislation were floated around for comments I can remember getting calls from some of our member company people who specifically asked about this point. They want this year, as Juanita said, to include this kind of language specifically to ensure that children are protected and that EPA is basically mandated to use the NAS recommendations and make sure these things are safe for those as well as other important subpopulation groups.

Ms. DUGGAN. A follow-on point that was discussed earlier is that, in addition, the bill does give EPA full flexibility and authority to take into account any data that they feel is important to protect a subpopulation, specifically infants and children. They are not prevented in any way, shape, or form from taking into account necessary information to make sure that tolerances protect the public health, and certainly we wouldn't want them to disregard that information.

So right now they take into account information on about 22 subpopulations, and certainly they could probably do that much better if they had the kind of data that was recommended by the NAS. But the notion that somehow this is preventing them from doing something they need to do to protect the public health for children I don't think is supported by the language in the bill.

Mr. BILIRAKIS. I was very surprised really at their attitude on this. The flexibility seems to be there, certainly the responsibility it seems to me is there, and they don't seem to want to pick up that responsibility unless the Congress actually mandates everything.

In your opinions—and we have another panel, and we will go into this with them—why are we getting this type of argument that H.R. 1627 does not provide adequate safeguards? Do you have any thinking in this regard?

Mr. STOLTE. For children specifically?

Mr. BILIRAKIS. Yes.

Mr. STOLTE. I don't know.

Ms. DUGGAN. I will make one comment, that I think the administration's comments have been fairly constructive in this Congress and have raised issues that I think are resolvable, and I commend them for narrowing their list of issues that they consider to be problematic from previous Congresses. I think that we could produce a piece of legislation very easily in this Congress and resolve some of the issues they have raised.

Mr. BILIRAKIS. I would hope so. I got that also from the testimony earlier, that they were willing to sit down and work some of these things out.

Okay. I thank you so very much and appreciate so much your taking the time to be here before us.

The next and last panel will consist of Mr. Erik Olson with the Natural Resources Defense Council; Mr. Jay Feldman, National Coalition Against the Misuse of Pesticides; Ms. Carolyn Brickey, executive director of the National Campaign for Pesticide Policy Reform; and Mr. Jay Vroom, president of the American Crop Protection Association.

As I always try to do, I want to thank this panel for their patience, for their willingness to sit through all of the other panels and await their turn. That is very good of you.

We will start out with Mr. Olson. Again, your full testimony, your written testimony, is made a part of the record, and I would appreciate very much if you would try to limit yourselves to as close to 5 minutes as possible.

Mr. Olson, please proceed.

STATEMENTS OF ERIK OLSON, ON BEHALF OF NATURAL RESOURCES DEFENSE COUNCIL; JAY FELDMAN, EXECUTIVE DIRECTOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES; CAROLYN BRICKEY, EXECUTIVE DIRECTOR, NATIONAL CAMPAIGN FOR PESTICIDE POLICY REFORM; AND JAY J. VROOM, PRESIDENT, AMERICAN CROP PROTECTION ASSOCIATION

Mr. OLSON. Thank you.

My name is Erik Olson. I'm a senior attorney with the Natural Resources Defense Council. We have worked on pesticide issues for over 20 years and were involved in the 1986 effort jointly with some in the industry to try to get FIFRA reform through and pesticide reform through. It fell apart, and then in 1988 we participated in the effort to get a narrowed-down bill through, and that was successful.

What I would like to talk about today rather than going through the written testimony in detail, since that is going to be entered into the record, are about some highlights. It is our basic viewpoint that current law is not adequately protecting public health and the environment and that we should not be talking about relaxing protections but about making sure that we have adequate protections for public health and for the environment.

I would like to get right down to the Bliley bill and some of the concerns that we have about the bill and, in particular, the Na-

tional Academy of Sciences recommendations. There are four major recommendations that I think are worth discussing that we believe, if H.R. 1627 were enacted, that EPA would have great difficulty if not be blocked from implementing these recommendations, and I will explain why.

First, the NAS recommended that multiple residues—what they said was, "All exposures to pesticides, dietary and nondietary, need to be considered when evaluating the potential risks to infants and children." Second, they said that the estimates of total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect—in other words, additive effects of multiple pesticides. In other words, you are supposed to look at the totality of exposure from all sources and from all the pesticides with a common toxic effect according to the Academy.

Our concern on that point is, first of all, that the bill as written appears to require a review of each individual residue, and, that is, the decision is made exclusively upon residue-by-residue determinations. That is on pages 57 and 59 of the bill. In other words, at least as we view it, EPA would have difficulty basing its regulatory decisions upon what the Academy recommended, which is looking at the totality of exposure from drinking water and from other sources as well as the food stuff. We believe that that Academy recommendation with changes in the bill could be implemented under the bill.

Second, we are also concerned about the FIFRA and Codex harmonization provisions which we believe would, at least arguably, override the health-based standard that is at least in theory in the bill. For example, the FIFRA risk/benefit analysis requirements and some of the Codex harmonization requirements could simply override the basic considerations of children that are mandated in other provisions of the bill.

Third, the National Academy committee, on page 9 recommended that, "An uncertainty factor of up to tenfold traditionally—similar to that traditionally used for fetal development toxicity should be considered when there is evidence of postnatal developmental toxicity or when the toxicity testing relative to children is not complete." In other words, there is a recommendation that there be an additional uncertainty factor where there are incomplete data. Our concern is, again, that that recommendation is not likely to be implemented under the bill.

Fourth, the Academy recommended that EPA should modify its decisionmaking process for setting tolerances so that it is based on health considerations rather than agricultural practices. Children should be able to eat a healthful diet—this is the Academy—containing legal residues without encroaching on safety margins. This goal should be kept clear. That is, we view that the most fundamental recommendation of Academy.

Our concern is that the benefits override provision which allows very broad considerations such as the ability of the pesticide to enable domestic growers to maintain the availability of adequate wholesome and economical food supplies and other benefits would simply render nugatory the consideration of children's and other health effects and that that broad override provision along with the broad FIFRA and Codex harmonization provisions would simply

render the health-based standards that are found elsewhere in the bill essentially without effect.

Finally, there is a recommendation of the Academy that age-related differences in exposure should be eliminated using 1-year age groupings. That is something that we believe should be required of the agency, and so far the agency hasn't implemented that.

I see my time has expired, and I had other things to say, but I'll leave those for questions.

Mr. BILIRAKIS. In the process probably you will be able to make those points.

Thank you, Mr. Olson.

Mr. OLSON. Thank you.

[The prepared statement of Erik Olson follows:]

PREPARED STATEMENT OF ERIK OLSON, ALBERT MEYERHOFF AND JENNIFER CURTIS ON BEHALF OF THE NATURAL RESOURCES DEFENSE COUNCIL

I. INTRODUCTION

I am Erik Olson, 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 possible amendments to the federal Food, Drug and Cosmetic Act and other pesticide laws. To briefly summarize:

- Current law is not adequately protecting public health and the environment from the adverse effects of pesticides. We should not relax public health and environmental safeguards.
- Conventional pesticide use in the United States has increased dramatically over the past three decades. EPA estimates that one out of every 10 public drinking water wells in the U.S. contains at least one pesticide; much of the Mississippi basin's water contains pesticides at levels above EPA health standards during the spring runoff; a large percentage of the food supply contains significant pesticide residues; and the "bugs are winning" due to increasing resistance to pesticides.
- The proposed Bliley bill (H.R. 1627) would undercut public health protection by: (1) failing to assure that children and infants are fully protected, through the complete implementation of the recommendations of the National Academy of Sciences; (2) failing to consider the broad array of pesticide risks from multiple pesticide residues and multiple sources of exposure; (3) locking into statute the override of health considerations by agricultural "benefits" and eliminating current curbs on carcinogens; (4) generally preempting States from protecting their citizens from dangerous residues; (5) requiring the "harmonization" of FIFRA, FFDCA, and Codex, to the detriment of specific and enforceable public health protections in the FFDCA; (6) failing to help farmers off the pesticide treadmill.
- 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.
- Numerous pesticides have been found to mimic the female hormone estrogen or to disrupt the endocrine system, wrecking havoc on these animals' reproductive ability.

HISTORICAL OVERVIEW

In quieter times, and following the leadership of the Eisenhower administration, a bipartisan Congress declared "war" on cancer, enacting laws like the National Cancer Attack Act and the Delaney Clause to the federal Food, Drug and Cosmetic Act. These and other laws reflected a national commitment to rid our society of this most pernicious disease—a disease that results in so much economic loss and untold human suffering. Since then, billions of public dollars have been expended seeking, usually unsuccessfully, a cure for cancer.

There have been some successes, particularly in prolonging the lives of people who have been diagnosed with cancer. Nevertheless, since 1950, the incidence of non-tobacco-related cancer has risen by more than 20 percent, with sharp increases in

childhood brain cancer, prostate and testicular cancer, among others. Breast cancer alone will now strike 1 in 8 American women during their lifetime. More than 60 million people in the United States (over one quarter of the population) will develop some form of cancer, from which 20 percent of the population will die.

The issue before this committee, and this Congress, can be simply stated: Is it now time to reduce this commitment to cancer prevention by rolling back protections provided to the American people against cancer-causing substances permitted in the food chain? The answer to us is a categorical NO and we strongly oppose H.R. 1627 on that basis. We believe to weaken already flawed federal pesticide laws would represent a breach of faith with the American public and that, instead, these laws need to be reformed and strengthened. The goal should be to achieve a reduced reliance by American agriculture on these most toxic of chemicals not to enact a statute written for the regulated industries.

A litany of studies have concluded our pesticide laws have been an abysmal failure in need of a complete overhaul. The *Environmental Protection Agency and the Regulation of Pesticides,* Senate Committee on the Judiciary, Subcommittee on Administrative Practice and Procedure, 94th Cong., 2d. Sess (1976); *Cancer-Causing Chemicals in Food,* House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigations, 95th Cong., 2d. Sess. (1978); GAO, *Delays and Unresolved Issues Plague New Pesticide Programs* (1980); *EPA Pesticide Regulatory Program Study,* House Committee on Agriculture, Subcommittee on Department Operations, Research and Foreign Agriculture, 97th Cong., 2d Sess. (1982); GAO, *Monitoring and Enforcing Food Safety—an Overview of Past Studies* (1983); *Problems Plague the Environmental Protection Agency's Pesticide Regulatory Activities,* Committee on Government Operations, 98th Cong., 2d Sess. (1984); GAO, *Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks* (1986); GAO, *Pesticides: Better Sampling and Enforcement Needed of Imported Food* (1986); and GAO, *Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues* (1986).

The failure of our pesticide laws has been due to the process itself as well as the acknowledged weaknesses of risk assessment, which is a half art/half science that, ironically, both representatives of industry and the environmental community seem to agree, is fraught with unreliability. There are inherent vagaries and uncertainties in quantitative risk assessment because, among other things, of the necessity of relying on data from animal studies and the generic inaccuracy of the process itself.

As a result, a few years ago, FDA Deputy Director Robert Scheuplein warned, government agencies "risk losing the integrity of the science and objectivity they need from it by continuing to suggest risk assessments are better than they are... We have not seen a scientific breakthrough which now permits the precise [estimation] of low-level cancer risks." 53 Fed. Reg. 41104, October 19, 1988.

Moreover, not only do risk assessments generally ignore the special risks toxic chemicals pose to infants and young children, by taking a chemical-by-chemical, use-by-use approach, they also fail to address the cumulative aspects of exposure to toxic substances. (National Research Council, *Pesticides in the Diets of Infants and Young Children,* 1993.) For example, there are more than 300 pesticidal active ingredients as well as an imperfectly examined large number of inert ingredients. For the most part, existing EPA pesticide food tolerances do not even attempt to calculate the aggregate human health risk presented, nor do they address the cumulative and synergistic effects on multiple pathways of exposure.

II. CONTINUING THE WAR ON CANCER

The only bright spot in this flawed regulatory regime is the Delaney Clause of the Food, Drug and Cosmetic Act. Enacted in 1958, the famous "clause" prohibits any food additive in processed food that "induces cancer in man or animal."

Since its enactment, the provisions of the Delaney Clause prohibiting carcinogens in processed foods have largely been ignored with respect to pesticides. EPA's consistent approach throughout the 1980s 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 post-harvest 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.

As the result of a consent judgment entered in the companion case to *Les,* entitled *People of the State of California* v. *Browner,* the Agency is now committed to implementing the Delaney Clause for specific pesticides, pursuant to a specific timetable, eliminating their presence in processed foods and, where necessary, in the relevant raw commodities as well (e.g., in oranges and orange juice). Under this settlement agreement, over the next decade, certain pesticides that are found by EPA to induce cancer in man or animal and that are present in processed foods (either through "concentration" when raw commodities are processed or from post-harvest application) will be phased out of use. A copy of that consent judgment and list of the initial pesticides to which it will apply is appended to this testimony.

III. 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) Accordingly, the 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 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 most 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.

Instead of maintaining the status quo on pesticide use, we 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.

IV. EXISTING PESTICIDE LAWS HAVE FAILED

Over the past thirty years:

- 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 U.S. 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 number one 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 fifteen 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 non farmers 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, California.

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 non-smoking 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).

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;
- 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.

V. 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.[1] 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.[2]

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

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

[2] *Soil and Water Quality,* p. 82.

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 U.S. 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.[3]

Numerous methods are available to reduce agriculture's use of and reliance on pesticides. The National Academy of Sciences in their report, *Alternative Agriculture* 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.[4]

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 U.S.[5] 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).

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 towards 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 towards technology transfer for pesticide reduction, including model demonstration farms and cost-share assistance.

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

(4) Complete pesticide record-keeping and use reporting.

(5) Establishment of pesticide reduction goals and programs for all federal agencies.

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

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

VI. 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 '70s 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

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

[4] *Alternative Agriculture.*

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

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:

- A Danish study of 21 industrialized countries documented a 50 percent drop in sperm count world-wide 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 sufferod 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 of 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."

VII. PROBLEMS WITH THE BLILEY BILL, H.R. 1627

We have been asked to testify on our views on H.R. 1627, the so-called "Food Quality Protection Act of 1995." While we are aware that some members of this Subcommittee support the bill, we regrettably must vigorously oppose it, because it is our belief that it would encourage even greater pesticide use and undercut even the weak current protections of the food supply from pesticide contamination.

The Bliley bill also would fail to assure that certain of the problems posed for infants and children by pesticides in foods, which were recognized by the National Academy of Sciences (NAS) in the important recent study entitled *Pesticides in the Diets of Infants and Children* (1993). We are strong supporters of good science, and believe that many of the proposals and issues raised by the Academy are inadequately addressed, or actually directly contradict certain provisions of the Bliley bill.

The Bliley bill's provisions revising the Federal Food, Drug, and Cosmetic Act's (FFDCA) pesticide residue-related provisions are fundamentally flawed, and would allow (and in some areas would even mandate) EPA to provide less protection of public health than is provided under current law. The bill also fails to require EPA to redress many of the agency's failures to redress key failures by identified by NAS in the pesticide residue regulation area, and actually locks into stone many of the problems that NAS noted were of most serious concern. The most important problems with the bill's FFDCA provisions are:

(1) Failure to Assure that Children and Infants are Fully Protected, Through the Complete Implementation of the Recommendations of the National Academy of Sciences

The bill fails to assure full implementation of the National Academy of Sciences' (NAS) consensus report, *Pesticides in the Diets of Infants and Children* (1993). This report found that pesticide tolerances are not based primarily on health considerations, and that generally the current regulatory system fails to give special consideration to the special vulnerabilities of infants and children to certain pesticides.

The Committee recommended that the EPA change its decision making to be based more on health considerations than on agricultural practices, and that several specific changes must bo made to assure the protection of young children. Among

other changes that are needed, the panel said, is the use of an additional 10 fold factor to protect infants and children when data from toxicity testing for children are incomplete, as they often are. Moreover, the panel recommended that EPA should base tolerances on consideration of exposure to multiple sources and multiple pesticides with the same or similar toxic effect.

As the Academy stated, "Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins." These and the other NAS recommendations should expressly be required to be followed in the legislation. Any legislation that is passed should require an explicit finding that exposure to legal limits is safe for infants and children.

(2) Failure to Consider the Broad Array of Pesticide Risks

The narrow inquiry required by the bill into the risks posed by a pesticide residue not only fails to account for vulnerable groups like infants and children. In addition, the bill does not allow consideration of multiple residues and multiple pesticides, and apparently fails to consider the threats posed by so-called "inert" ingredients (such as known cancer-causing chemicals like benzene).

Thus, under the bill's approach, for example, a pesticide applied to scores of crops could be used on each of those crops at a given risk level, posing total risks many times higher than the "negligible" risk level, yet this cumulative risk would not be considered. This forces a highly unrealistic set of risk estimates that bear little resemblance to real world exposures, and would consistently understate real risks.

(3) Locking into Statute the Override of Health Considerations By Agricultural Benefits

H.R. 1627 enshrines into law the notion that even if a pesticide residue poses a significant risk to the public, the residue is allowed if it is said to have sufficient "benefits." While the bill as drafted apparently allows each pesticide residue's *risks* to be calculated *on a narrow basis,* its *benefits* are to be calculated based on an *extraordinarily broad* set of principles, such as "enabl[ing) domestic growers to maintain the availability of an adequate, wholesome, and economical food supply... The Bliley bill allows so much leeway that virtually any risk could arguably be allowed as acceptable because of asserted benefits.

(4) Preempting States from Protecting their Citizens

In these times when much is being said about the need to return authority to the states, it is ironic that the bill would weaken current law by generally preempting states from adopting tolerances more stringent than any new EPA tolerances for pesticides. States always have had the authority to adopt such tolerances, and only in a few well-justified cases have states used this authority. Like the bill's local pesticide use control preemption provision, this state tolerance preemption provision is unjustified and unnecessary.

Not only have states only sparingly used their longstanding authority to adopt these tolerances exclusively in the most limited and necessary circumstances, but any ill-conceived state tolerance that theoretically could be adopted could be challenged in state courts as unjustified or in federal courts as an undue burden on interstate commerce under the Commerce Clause. The only exception to the ban on stricter state tolerances would be that EPA could allow a state to adopt such a tolerance if EPA finds there are "compelling local conditions" and certain other hurdles are jumped. How are states to respond if EPA has failed to act with respect to a highly dangerous pesticide residue such as the EDB problem in California, if this bill were enacted?

(5) Harmonization and Coordination of FIFRA, FFDCA, and Codex

We are deeply concerned that the bill's provisions requiring that essentially the FFDCA's health-oriented requirements will be harmonized with, and generally it appears subservient to, the FIFRA and Codex provisions is likely to undercut public health protection and encourage litigation to weaken EPA tolerances for pesticides.

(6) Failure to Help Farmers Off the Pesticide Treadmill

The Bliley bill, by essentially maintaining the status quo for pesticide use and weakening current law, fails to help farmers off the pesticide treadmill. It is important that incentives be provided and that dangerous pesticides be phased out to create the necessary dynamic to encourage the use of less toxic pesticides and non-pesticide alternatives. This bill, unfortunately, does nothing to move the country in this direction.

WHITE PAPER: THE NEED FOR A PHASE-OUT OF CARCINOGENIC PESTICIDE RESIDUES—NATURAL RESOURCES DEFENSE COUNCIL

Introduction and Summary

There is now an opportunity for a major shift in the way the nation's agricultural system does business—to help farmers and consumers. As a nation, we must put the "pollution prevention" and "pesticide use reduction" concepts embraced by the Clinton Administration to work, by taking immediate and direct steps to shift away from the use of older, more dangerous, cancer-causing pesticides, and towards alternative pest management approaches that pose less risk. One central driving force in this shift should be the adoption of the principle that we should not be intentionally adding carcinogens to our food supply. We should be phasing out the use of carcinogens and phasing in the use of alternatives.

The technical and scientific reasons for a phase-out/phase-in are many. There are substantial uncertainties inherent in quantitative risk assessment due to data gaps and methodological problems that necessitate a phase out of carcinogenic pesticides:

- As the National Academy of Sciences' recent report on pesticides in children's food emphasized, risk assessments used to determine, for example, whether a pesticide supposedly poses a "one in a million risk," do not address *cumulative* risk posed by that pesticide from all sources of exposure (such as air, drinking water, food, etc.), yet such multiple sources of exposure should be considered.
- The Academy also highlighted that risk assessments fail to consider the risks posed by the *interactions of multiple cancer-causing or otherwise toxic pesticides* on the same food or in the complete diet. Since a single meal may contain ten or more pesticide residues, this is a critical failure.
- Even if a pesticide were said to pose a "one in a million" risk in food, there generally are far greater risks posed by the pesticide to farmers, farm workers, and the chemical workers who make the pesticide.
- It is important to consider that some subpopulations, including infants, children, and poor poople (especially poor children) are likely at especially high risk but accurate prediction of these risks is severely hampered by serious gaps in exposure, toxicity, sensitivity, and interactive effects data.

Ultimately, as in the case of CFCs, methyl bromide, and other ozone depleters, there should be a phase out of food tolerances for carcinogenic pesticides over the next five to seven years. Those carcinogenic food use pesticides whose tolerances can most readily be phased out should be revoked first, based upon a schedule established by EPA considering the availability of alternatives. Upon a finding by EPA that there are safer alternative methods of pest management that would not lead to a carcinogenic food residue, EPA should be required to revoke the tolerance for that carcinogenic pesticide residue. No new tolerances for pesticides that are carcinogens should be issued.

Tolerances for pesticides now categorized as A, B, and "possible" human carcinogens whose risks EPA has determined are quantifiable ("Cq") should be phased out no later than 7 years from the date of enactment. Any tolerance for a pesticide which EPA has already determined is a possible human carcinogen but whose risks are not quantifiable ("unquantifiable C") should be covered by the phaseout on the same date as a Cq pesticide unless the registrant demonstrated to EPA's satisfaction that its chemical is probably not a carcinogen. Food tolerances for existing pesticides determined to be A, B, or C carcinogens for the first time after the date of enactment should be phased out within 7 years from such determination. These phase outs would result in the revocation of the carcinogenic pesticide's tolerance by operation of law without further EPA action at the end of the "sunset" period. The law should provide a clear process for one-stop EPA determinations of the category of the pesticide. Pending the ultimate phase-out, progress must be made towards implementing alternatives and eliminating the carcinogenic pesticide's tolerance.

In tandem with this phase-out of carcinogenic pesticide tolerances, EPA and USDA should be required to adopt an aggressive national program of research, development, and local demonstration to identify and assure the availability of alternatives to the pesticides subject to the tolerance phase out.

Why a Phase-out is Needed

Quantitative risk assessment remains part art, part science. There are numerous areas of uncertainty involved in developing an estimate of the risk potentially posed by a pesticide residue or by any other environmental pollutant. Uncertainties derive from a broad array of problems, including gaps or uncertainties in toxicological data, our failure to understand the differences between the effects of a chemical on laboratory animals versus humans, problems in determining what subpopulations such

as children are at special risk, difficulties in translating from high dose to low dose exposures, the lack of hard data on actual exposure to the chemical from multiple sources, and many other problems.

When these uncertainties arise, the risk assessor seeks to make reasonable assumptions about the missing data, and plugs those values, and sometimes "safety factors" intended to try to compensate for possible underestimation of risks, in reaching the final risk estimates. However, the uncertainties in risk estimates can be large (orders of magnitude) when the data gaps are significant. Moreover, for some data gaps—such as the lack of information on interactive effects of multiple carcinogens consumed in the real world—risk assessment traditionally cannot consider these problems. As the National Academy of Sciences has made clear, in many ways standard risk assessments may seriously underestimate risks, particularly for infants and children. Among the most important sources of uncertainty and possible underestimation of risks in classic food safety risk assessments are:

Interactive Effects: Complex Mixtures of Pesticides and other Toxins

- Unlike laboratory rats, people generally go through their lives breathing, eating, and drinking an extraordinarily complex mixture of toxic and potentially carcinogenic substances, both natural and anthropogenic. For example, pesticide residue data indicate that in a single meal, a person can easily consume five, ten, or more pesticide residues in his or her food.
- The cumulative toxicological effects of pesticide active ingredients, "inert" ingredients, and other carcinogens from multiple sources should be considered, but are not.
- Good science would dictate that the real world of exposure to complex mixtures must be the basis of our pesticide policies. Yet synergism, additivity, and other possible joint effects of carcinogens in foods generally are not considered in risk assessments. Scientific literature indicates that in some cases, such as with asbestos and smoking, radiation and smoking, or smoking and alcohol, synergism of carcinogenic effect have been shown; in other cases, additivity or other interactive effects are found.
- Synergistic effects of pesticides to animals as acute toxins (e.g. malathion and EPN) have been shown in well-documented toxicological studies, but few if any studies have sought to document whether pesticides have additive, synergistic, or antagonistic effects in causing cancer.[1] Pesticide users and registrants sometimes rely upon and use synergistic toxic effects of two or more pesticides in controlling pests by applying more than one pesticide at once (known as "pesticide synergists"), to get more than an additive "kill."[2] There is no *a priori* reason to suspect that synergistic toxic effect is necessarily limited to target organisms.

Underestimates of Risks to Children, Minorities, the Poor, and Other Subpopulations Due Consideration of "Average" Consumers and Gaps in Exposure Data

- Accurate data regarding the true levels of exposure of all important subpopulations to individual pesticides and on exposure to complex mixtures of pesticides and other carcinogens, are virtually impossible to obtain. Thus, traditional risk assessment sets levels based on "average" consumers—failing to protect the most exposed subpopulations.
- Exposure to each pesticide from all media and sources, such as commercially purchased food, sport fish, drinking water, air drift, indoor and outdoor air pollution, occupational exposure and so forth, ideally should be considered, but generally are not. Often data on key subpopulations' actual exposure is virtually nonexistent so accurate risk assessment for those people is impossible.
- As the National Academy of Sciences pointed out, children tend to eat large amounts of certain foods—in many cases an order of magnitude or more larger amounts of some foods such as certain fruits and juices. Thus, pesticide residues on those foods pose a disproportionately high risk to children.
- Some population subgroups, such as members of certain ethnic or religious minorities who eat a disproportionately large amount of certain foods, also may be at especially high risk.
- The National Academy of Sciences report on children and pesticides pointed out that children living in poverty may be at special risk due to higher exposure

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[1] *See, e.g.*, Doull, J., Klaassen, C.D., & Amdur, M.O., *Casarett and Doull' Toxicology: The Basic Science of Poisons* (Macmillan, Second Edition, 1980); Murphy, S.D., Costa, L.G., & Scwab, B.W., "Pesticide Interactions and Development of Tolerance," in *Effects of Chronic Exposures to Pesticides on Animal Systems*, J.E. Chambers & J.D. Yarbrough, eds., pages 227-241. (Raven, 1982).

[2] Hayes, W.J. & E.R. Laws, Jr., *Handbook of Pesticide Toxicology*, vol. 3, 1508-1510 (Academic Press, 1991).

to toxins in more polluted neighborhoods, poor nutrition, and otherwise compromised health.[3] Thus, the Academy noted, "the combined effect of poorer health status and of likely higher exposure to environmental toxicants suggests that the further burden of pesticide exposure [to poor children) could lead to toxic effects that do not produce effects in other children. Therefore, one might expect that adverse effects of pesticides, whether acute or chronic, might be magnified in this subpopulation."[4]

- There may be "foodsheds", or areas of the country where people tend to eat fresh commodities primarily from local growers. Those who often eat local fresh foods soon after the crop is picked, and who live in regions where crops are more heavily treated with certain pesticides (due, for example, to local climatic or pest infestation conditions), could be exposed to pesticide residues that may be substantially higher than the national average. For example, milk products and many fresh fruits and vegetables may be distributed locally almost immediately after they are picked or produced, leaving little time for residue degradation and potentially creating pockets of relatively heavily pesticide residue-laden foods.

Underestimation of Risks Due to Failure to Consider Highly Sensitive Subpopulations

- Risk assessments generally are not specially designed to discuss or address the risks of pesticide exposure to especially sensitive subpopulations due to their sensitivity. As the National Academy of Sciences has recently emphasized, and as the scientific literature has documented, there are special chemical sensitivities of certain subpopulations, including the young, to certain neurotoxins and other chemicals.[5] Studies also have shown that the young are more susceptible to many carcinogens than are adults, due to physiological differences of the young compared to the normal adult population and certain other factors.[6]
- Literature regarding drug and other chemical allergies of certain sensitive individuals suggests that certain subpopulations in the general adult population are especially susceptible to certain chemicals.[7] Pesticides could be among the chemicals to which such allergic or idiosyncratic, highly sensitive reactions may occur.

"Upstream Effects of Carcinogenic Pesticide Use on Farmers and Farmworkers Are Highly Significant and Often Forgotten

- A mounting body of epidemiological evidence shows that farmers and farmworkers are at especially high risk of certain cancers associated with their high exposure to certain carcinogenic pesticides.[8]

Thus, in many ways risk assessment, due to data gaps, cannot fully consider factors that lead to substantial underestimation of risks. Indeed, many of these factors, such as cumulative, interactive, and synergistic exposure and effects, highly exposed and highly sensitive subpopulations such as children and the poor, and due to the impacts of occupational exposure, there is no real and readily apparent solution that would allow us to say with confidence that a pesticide poses a "negligible risk" in foods even if one accepts that concept as appropriate. Moreover, this approach for foods fails to consider the substantial upstream effects of pesticides on farmers and farmworkers. Therefore, a phase-out of the intentional addition of cancer-causing pesticides to foods, and a phase-in of safer alternatives, is needed.

A Review of Real World Exposure to Multiple Pesticide Residues and Other Potential Carcinogens from Multiple Sources

It is important to recognize that generally, when we discuss the risks of a pesticide on food, we are discussing only a very narrow subset of the risks. Moreover as noted above, EPA's risk as assessments for pesticides generally calculate cancer risks as assuming that a person is exposed to one pesticide at a time.

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[3] NAS, NRC, *Pesticides in the Diets of Infants and Children*, at 343-44.

[4] *Ibid.* at 344.

[5] *See, e.g.*, National Academy of Sciences, National Research Council, *Pesticides in the Diets of Infants and Children* (1993); Calabrese, E.J. *Age and Susceptibility to Toxic Substances*, (John Wiley & Sons, 1986); World Health Organization, *Environmental Criteria 59, Principles for Evaluating Health Risks from Chemicals During Infancy and Early Childhood: The Need for a Special Approach*, (Geneva, 1986).

[6] *See*, Calabrese, *supra*.

[7] *See, Casarett & Doull's Toxicology*, at 15-16.

[8] For a summary of some of this evidence, *see*, M. Moses, "Cancer in Humans and Potential Occupational and Environmental Exposure to Pesticides: Selected Epidemiological Studies and Case Reports," *AAOHN Journal*, v. 37, p. 131-36 (March, 1989); NRDC, *After Silent Spring: The Unsolved Problems of Pesticide Use in the United States*, pp. 8-14 (June, 1993).

ontrast, in the real w d we are all exposed to a complex mixture of carcino-
pesticides and other c r-causing chemicals. Generally, EPA has not sought
luate the cancer ri d by the use in the food supply of not just one pes-
but the nearly 300 "active ingredients" (and an imperfectly examined large
ber of "inerts," i.e., "inert" as far as target pests are concerned, although many
ose "inert" chemicals are quite humanly "active"). EPA has said that approxi-
ely 70 pesticides now in use on food are probable or possible human carcinogens.
ny experts are concerned that this percentage will grow when reregistration is
plete.

It also is important to recognize that food-use chemicals are, of course, not the
ly pesticides to which people are exposed, nor is food the only route of exposure
o food use pesticides. Many of us live, work, and recreate in locations in which pes-
icides are used and to which we may be exposed by breathing, dermally, and in
our drinking water. Moreover, there are 53,000 chemicals used commercially in the
U.S.; for 86% of these, we do not have even modest toxicological data upon which
to base any assessment of safety, acute, chronic, or otherwise.[9] Examining a subset
of the 14% of the non-pesticide chemicals for which some toxicological data exist,
we find many more suspect carcinogens. For example, cosmetics contribute anther
125 possible or probable human carcinogens.[10] In addition, there are numerous air-
borne carcinogens, carcinogens in drinking water (i.e., that which we combine with
our food when we cook it),[11] in the work place, in drugs, in tobacco, and so forth.
The levels of exposure to carcinogens in these other media (especially in the work
place) are often greater by several orders of magnitude.[12]

Risk assessments in the pesticide food safety arena generally fail to consider this
reality. It is rarely, if ever, explicitly emphasized, that a 1/1 million risk cited for
a carcinogenic pesticide on food is derived from animal experiments in which the
animals are knowingly exposed to *no other carcinogens other than the one in ques-
tion.*[13] By contrast, humans are potentially exposed to more than 60 carcinogens
just in food (a number that likely will increase when all the toxicological data come
in).[14]

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[9] Grisham, Health Aspects of the Disposal of Waste Chemicals, 182 (1986) (hereafter, "Gris-
ham").

[10] Hutt & Merrill, Food and Drug Law, 819 (2d ed. 1991).

[11] As of 1981, the National Academy of Sciences had identified at least 21 carcinogens in
drinking water. Hoel & Krump, "Water Borne Carcinogens: A Scientist's View," in Crandall &
Lave, eds., The Scientific Basis of Health and Safety Regulation, at 173, 180-82 (1981). "Esti-
mates of the risks (of each these individual carcinogens) were obtained from controlled animal
studies and apply specifically to risks of chemicals in the absence of other carcinogens. The mag-
nitude of such effects cannot be predicted from data on individual carcinogens." *Id.* at 182.
"[A]dding these weighted risks together would yield an estimate of the total carcinogenic effect
of these chemicals. However, this would probably underestimate the total carcinogenic risk from
drinking water since the estimate would not include the carcinogenic potential of the chemicals
in drinking water not yet identified or not yet tested for carcinogenicity. Approximately 90 per-
cent of the total organic content in drinking water falls into this category." *Id.* at 182-83.

[12] Generally, exposure to carcinogens on the job is permitted at a much higher level than in
food. For example, OSHA allows exposure to arsenic at a level that results in a QRA of 8,000
lung cancers per million exposed workers. *ASARCO* v. *OSHA*, 746 F.2d 483 (9th Cir. 1984); Hutt
& Merrill, *supra*, at 938. Persistent low level exposures may be worse than intermittent or sin-
gle exposures at a higher level. Yet, there is substantial scientific support for the "one-hit" the-
ory—that under some circumstances, a *single* exposure to some carcinogens is enough to cause
cancer. See e.g., Scheuplien, "Risk Assessment and Food Safety: A Scientist's and Regulator's
View," 42 *Food, Drug & Cosmetic Law Jour.* 237, 241 nn. 15 & 16 (1987).

[13] The comprehensive NAS report, *Complex Mixtures: Methods for In Vivo Testing*, (1988)
(hereafter "NAS, *Complex Mixtures*") at 5, explains why:

> Toxicity testing has traditionally studied chemical compounds one at time, for various reasons:
> dealing with agents singly has been more convenient to investigators; physiochemical properties
> of single agents were often more readily defined; dosage could be more easily controlled; biologi-
> cal fate could usually be monitored in a straightforward manner; concentrations in air, water,
> and tissue could be accurately measured; target-organ toxicity was predictable on the basis of
> experience with agents related to the one in question; and relevant data were often available
> from human occupational exposures.

[14] NAS, *Complex Mixtures*, at 1, begins as follows: "People are seldom exposed to single chemi-
cals. Most substances to which people are exposed, whether naturally or artificially produced,
are mixtures of chemicals. Mixtures that are of particular concern include chemicals generated
in fire, hazardous wastes, pesticides, drinking water..."

FDA has recognized that "[t]he approval of a carcinogen[] does *not* include consideration o
the potential interaction or synergy between an approved compound and any other substanc
or substances to which people are exposed. *Certainly, the more approved carcinogenic compounc
that are marketed the greater is the likelihood of cancer induction in people.*" 50 Fed. Reg. 455
(10/31/85), quoted in Hutt & Merrill, *supra*, 900-01 (emphasis added). This notion was emph

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The introduction to a recent IARC symposium on the subject pointed out that "[m]ost chemical exposures in the real world involve complex mixtures rather than single agents, but the scientific data-base for these mixtures is generated almost entirely from studies of individual agents."[15] While it is indeed true that "[e]stimating the human cancer risks of exposure to complex mixtures presents formidable methodological problems... such exposures are thought to account for a large proportion of cancers, in particular because of widespread exposures to such mixtures within populations.[16]

In short, "good science" should emphasize *and* do its best to account for the reality that in contrast to laboratory animals, humans are exposed to a multiplicity of carcinogens, a reality that implicates the very important concept of toxic interaction. As one expert in the area notes:

> A toxic interaction is defined as a condition in which two or more chemicals result in a qualitatively or quantitatively alterod biological response relative to that predicted from the action of the individual chemicals. For any exposure, both exogenous and endogenous interactions may result in either: (a) additivity—where the combined effect is the sum of the effects of the individual agents; (b) synergism—where the combined effect is greater than the sum of the effects of the individual agents; (c) potentiation—where one component enhances the effect of the other [e.g., carcinogenic promoters and initiators]; or (4) antagonism—where the combined effect is less than the sum of the effects of the individual agents.[17]

The effect will vary, depending upon the particular chemicals in question. Indeed, the effect can vary with the same chemical; if exposure to chemical A precedes exposure to B, the effect can be different than if the exposure is the other way around.[18]

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sized in, Environ Corp., Elements of Toxicology and Chemical Risk Assessment: A Handbook for Attorneys and Decision Makers (1986), at 53 (emphasis added):

The basic problem can be stated simply: we can measure the risks posed by chemicals only under certain highly restricted conditions of exposure, but we *need* knowledge of (i.e., [we need to] assess) the risks they *may* pose under conditions of exposure that fall *out of the range of current measurement capabilities... The most serious potential danger associated with the use of risk assessment concerns the failure to recognize its limitations and uncertainties."*

[15] Viano, Sorsa, & McMichael, Complex Mixtures and Cancer Risk, 1 (WHO, IARC 1990) hereafter cited as "IARC, *Complex Mixtures.*"

[16] *Id.* at 8.

[17] Grisham, at 183. See also, NAS, *Complex Mixtures,* 1-29, 185-201; Kaldor & L'Abbe, "Interaction Between Human Carcinogens," and Williams, "Chemical Mixtures and Interactive Carcinogenesis: In Vitro Studies," in IARC, *Complex Mixtures,* at 35-43, 107-12; Murphy, "General Principles in the Assessment of Toxicity of Chemical Mixtures," 48 *Environ. Health Perspectives,* 141-44 (1983); Chen, Gaylor & Kodell, "Explanation of the Joint Risk from Multiple-Compound Exposure Based on Single-Compound Experiments," 10 *Risk Analysis* 285 (1990); Calif. Dept. of Health Services, Guidelines for Chemical Carcinogen Risk Assessments and Their Scientific Rationale, p. B-7 (1985).

[18] "Both the sequencing and the frequency of events in a combined exposure may contribute to the mechanism of toxic interaction. The interaction between chemicals and multiple environmental factors can result in an increase in the incidence of some human cancers that is greater than that expected from an exposure to a single carcinogen. The chemical induction of tumors is considered to be a multi-stage phenomenon, requiring either repetitive exposure to a single agent followed by promotion from a secondary agent at a later time. Initiation takes place rapidly and is considered to be essentially irreversible, while promotion may occur months or even years later." (Grisham, at 183-84 (citations omitted)

In addition, "[i]t is commonly believed that... the theoretical effect of two carcinogens acting at different stages can be substantially altered by the timing of the two exposure periods, resulting in a spectrum of risks ranging from additive to greater than multiplicative." (Brown & Chu, "Additive and Multiplicative Models and Multistage Carcinogenesis Theory," 9 *Risk Analysis,* 99 (1989).)

"The concepts of initiation and promotion were derived from empirical observations of experimental tumorigenesis... in which the administration of an ineffective dose of a known carcinogen, followed by repetitive treatment with another agent [a non-carcinogenic promoter] elicits the appearance of many tumors. Application of this second agent alone causes only a few tumors." (Trosko & Chang, "Role of Tumor Promotion in Affecting the Multi-Hit Nature of Carcinogenesis."

"The concepts of initiation, promotion, and progression have evolved to explain the observation that tumors could be induced by application of a subthreshold dose of a carcinogen (the initiation phase) followed by repetitive treatment with a noncarcinogen (the promotion phage)."*Id.* at 262. "If PBB is given to a rat prior to administration of a carcinogen, for example AAF or DMBA, it will actually protect the animal from the initiating potential of these particular compounds. The same compound, given in the exact same way, but after initiation, acts as a promoter. Here we have a real dilemma in that it is going to be imposeible to put a red flag or green flag on a molecule just by virtue of its structure. We have to make our assessment in the context of the biological behavior of the compound. Why [are] these kinds of chemicals acting

One study was conducted, for example, on the acute toxic interactions of 13 organophosphorous pesticides. The investigators found that 21 pairs had additive toxicity, 18 pairs had less than additive toxicity, and four pairs had synergistic toxicity.[19]

To get out of the conceptual realm and into reality, that is. to determine the actual interactive effect of a given pesticide, at the most extreme, it would be necessary to conduct separate animal feeding tests with it, plus one other, through the 60,000 other chemicals presently in use. The cost of doing these experiments would be astronomical. But even then, bearing the costs would only tell us more about the interactive effect of *two* chemicals. The costs of conducting the tests for combinations of 3, 4, 5, 6, etc. chemicals make such testing unrealistic.[20]

Conclusion

Thus, there are major uncertainties using quantitative risk assessment for pesticides, ranging from the inability to grapple with cumulative and interactive effects of the pesticides we are exposed to daily, the impacts on especially sensitive subpopulations such as children and especially poor children, the lack of exposure data for key subpopulations, and the failure to consider "up stream" effects on workers and farmers. Therefore, without the ability to pinpoint with accuracy the actual level of risk posed by cancer causing pesticides, a "pollution prevention" approach that seeks to cut off the problem at its source through the phase out of the carcinogens and phase in of alternatives is vitally important.

Mr. BILIRAKIS. Mr. Feldman.

STATEMENT OF JAY FELDMAN

Mr. FELDMAN. Good afternoon, Mr. Chairman.

My name is Jay Feldman. I'm executive director of the National Coalition Against the Misuse of Pesticides. We were founded in 1981 to bridge the concerns of farmers, consumers, and environmental interests in an effort to reduce and, where possible, eliminate reliance on toxic materials and promote alternative strategies for pest management. I'm also here today representing Beyond Pesticides, which is a new grassroots coalition which was founded last year, a coalition of environmental, farm labor, and sustainable agriculture, and public health groups throughout the United States.

In terms of H.R. 1627, we are operating under the premise that it is wrong at this juncture to weaken a food safety and pesticide regulatory system that science has told us is already not working. In the written statement we point to the various factors that contribute to background on this particular point: What are the scientific studies that document that we are deficient as a Nation in addressing serious problems such as cancer, which strikes 1 in 3, kills 1 in 4, infertility, childhood cancers such as brain cancers, soft tissue sarcoma, et cetera.

Children need to be better protected than the provisions provide for. H.R. 1627 does not deliver on this need, although we recognize the improvements over last year's version of the bill.

We believe it is extremely disingenuous to testify before this committee that it is important to protect children, give EPA the discre-

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as anti-initiators under one set of conditions, and as anti-promoters in one organ system, but as promoters in another organ system of the same species?" *Id.* at 284.

"A single promoter has been shown to intensify the effects of a particular carcinogen by a factor of 1,000." Page, Harris, and Bruser, "Waterborne Carcinogens: An Economist's View," in Crandall & Lave, *supra*, n. 1, at 197, 201, citing Bingham & Falk, "Environmental Carcinogens: The Modifying Effects of Carcinogens on the Threshold Response," 19 *Arch. of Environ. Health,* 779-83 (1969).

[19] *Casarett and Doull's Toxicology, supra,* at 398.

[20] Testing all of the interactions between just 10 chemicals would require 1,013 tests. See the EPA-sponsored NAS study, *Drinking Water and Health: Selected Issues in Risk Assessment,* vol. 9, pp. 121-22 (1989).

tionary authority to do that, and not provide the resources necessary to achieve that end. Everyone sitting in this room, previous witnesses, know full well that both USDA and EPA lack the resources necessary to generate the exposure data that is required to carry out the provisions in the bill, and therefore we believe if the committee is sincere about achieving this standard of childhood protection that the necessary resources would have to be designated.

The second point I would like to make is that risk/benefit analysis is not a protective public health standard, and to suggest that it is in the context of this bill, I think, is misleading. Risk assessment methodologies for the most part reflect real life situations.

A previous witness indicated the multiple exposure issue. There are a whole range of problems associated with risk assessment that go to the questions of synergistic effects: the fact that EPA is behind schedule on collecting the necessary data, the integrity of the test data, differences in professional judgment; and, finally, the benefits analysis in H.R. 1627 does not consider the full cost of pesticide use.

It has been mentioned previously that low-income consumer would be adversely impacted by maintaining a Delaney type clause. The reality is, what happens to farm workers, who are among the lowest paid of workers in the United States, and what happens to people that are in low-income communities that are adversely affected by drift and other factors concerning pesticide exposure?

Finally, I would like to get to the Delaney clause in the context of risk assessment. The Delaney clause we believe is a sound scientific concept, and I really ask you to consider that in the context of our written statement. Given the history here and the previous testimony you have heard, there are a couple of points that need to be made.

Increases in technological capacity to detect smaller and smaller quantities or levels of chemicals to the part per trillion level or greater does not negate the critical scientific need to establish a threshold safety level. This is the point at which an adverse effect is promoted or initiated, and the fact of the matter is, despite what I think one previous witness said, we do not know the mechanism of cancer. I mean physicians can tell us that. The mechanism of cancer is not known. That has not changed since 1958 and the adoption of the Delaney Clause. The only thing that has changed is our technological capability to detect smaller and smaller levels. That doesn't say that the part per trillion level is not initiating or promoting. Delaney is a public health provision that errs on the side of safety, protecting adverse impacts.

I urge you to look carefully at the risk assessment models that are proposed as possible replacements for Delaney, and it should be noted here that H.R. 1627 does not define negligible risk clearly; and, second, the decisionmaking process which is referred to as risk assessment and seems to have the scientific mystique about it, as indicated by a previous witness, comes down to a question of toxicological philosophy. That is what we were told earlier by one of the witnesses. So we need to consider real life situations, we need to consider exposure to multiple pesticide residues, we need to look at a range of factors as to the crudeness of the models.

Finally, Mr. Chairman, I urge this committee not to betray the basic concept of States' rights that is incorporated into our U.S. Constitution. The provision in H.R. 1627 to override the authority of States to adopt more stringent standards flies in the face of everything I think this committee would like to achieve, which is increased protection of public health and safety.

We as a coalition believe that we can achieve our pest management goals without the heavy reliance that we now have on pesticides in our society today. We believe very strongly that we need to protect the rights of farmers to farm, the rights of farmers to achieve a profitable and productive crop, but we believe we need to take a much closer look than this bill employs and assumes the need for, the necessity for, cancer-causing and other hazardous pesticides in the food production system.

Thank you.

[The prepared statement of Jay Feldman follows:]

PREPARED STATEMENT OF JAY FELDMAN, EXECUTIVE DIRECTOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Good morning Mr. Chairman and members of the Subcommittee. I am Jay Feldman, Executive Director of the National Coalition Against the Misuse of Pesticides (NCAMP). We appreciate the opportunity to testify before the Subcommittee today on a matter of utmost importance to the American farmer and consumer—food safety and pesticides.

NCAMP was founded in 1981 to bridge farmer, consumer and environmental interests in an effort to reduce and where possible eliminate reliance on toxic materials in pest management systems. What links us is a concern for the health of our families and the protection of the environment. Our membership spans the 50 states and groups around the world.

I am also here today representing Beyond Pesticides, formed in 1994 as a national grassroots coalition of environmental, farm labor, sustainable agriculture and public health groups throughout the country. At this time, over 150 groups from across the country, including women's groups, children's advocacy and environmental justice groups, have joined with the coalition and endorsed its mission. Beyond Pesticides seeks to prevent the avoidable real life disasters and compounding economic costs that result from pesticide poisoning and contamination. As a coalition, we seek strong public health standards to protect human health and the environment, while strongly promoting the adoption of alternatives to pesticides.

For the purposes of this hearing, we will focus on provisions in H.R. 1627, the *Food Quality Protection Act of 1995,* that pertain to amendments to the Federal Food Drug and Cosmetic Act. We are operating on the basis premise that it is wrong to weaken a food safety and pesticide regulatory system that science has told us is already not protecting us. In other words, we should be meeting here today to discuss strengthening amendments rather than the provisions of this bill which will only serve to weaken current protections in law.

In this context, we would like to share with the Subcommittee some of the thematic problems with H.R. 1627. To that end, we believe the following should be considered:

> The law should be strengthened to accommodate increased scientific knowledge. H.R. 1627 ignores recent scientific findings linking pesticides to adverse health effects.
>
> Risk-benefit analysis is not protective of public health. H.R. 1627 wrongly embraces risk-benefit analysis as a public health tool.
>
> State and local authority to exceed federal standards is essential to good public policy on health and safety and democratic ideals. H.R. 1627 betrays the basic principle of states' rights.

We provide you with the basis of these positions below:

I. The law should be strengthened to accommodate increased scientific knowledge. H.R. 1627 ignores recent scientific findings linking pesticides to adverse health effects. The scientific data suggest that we, as a nation, have a real environmental health problem that can be significan controlled and reversed with a clear na-

tional commitment to alternative pest management strategies that do not rely on pesticides.

a. Scientific studies document a serious health and environmental threat from pesticides. We are here today to address the serious matter of protecting human health and the environment, while ensuring that the necessary pest management tools are available to pest managers. We are having this discussion in the context of increasing pesticide use and increasing reliance on pesticides. In 1994, over 2 billion pounds of pesticides were used, including conventional pesticides, wood preservatives and disinfectants.[1]

We believe that the Subcommittee and Congress must address food safety and pesticide questions in the context of human and environmental health, as well as sustainable pest management strategies. This need exists with a backdrop of adverse human health and environmental effects that in many cases is reaching crisis proportions.

- Cancer now strikes one in three persons and kills one in four.[2]
- The rates of illness and mortality associated with cancer are rising. Devra Davis, formerly with NAS Board on Toxicology and now a senior scientific advisor the Secretary of Health at DHHS, said in her Oct. 21, 1993 congressional testimony, "We found that industrial countries' rates of cancer mortality increased from 1968 to 1986 for a number of sites, including melanoma, prostate, non-Hodgkins lymphoma, multiple myeloma, breast, brain and kidney cancer." The NRC found that all forms of cancer except lung and stomach are increasing in people over 54—not attributable to increased detection capability.[3]
- Dramatic worldwide decline in male sperm counts over the last 50 years.[4]
- Reproductive failures in wildlife species ranging from alligators in Florida to polar bears in Alaska.[5]
- Childhood brain cancer,[6] childhood leukemia and soft tissue sarcomas[7] associated with homes where pesticides are used. 1991 National Cancer Institute epidemiological data should the rate of childhood malignancies climbed almost 11% from 1973 to 1988—not a function of better reporting.[8]

We do not know as much as we should about the chemicals that H.R. 1627 would regulate. To err on the side of more use or continued heavy reliance on pesticides is to ignore the signals that are crying out to us. One of the most striking signals is the potential impact of endocrine-disrupting chemicals. Louis Guillette, Jr., Ph.D., a wildlife biologist who has studied estrogenic pesticides writes, "Studies using this [systematic methodologies of epidemiology—'ecoepidemiology'] approach have now provided strong evidence that various environmental contaminants disrupt the embryonic development of the reproductive system of numerous wildlife species, permanently altering the reproductive capabilities of these individuals."[9] Numerous pesticides are included among the environmental contaminants.

b. Children need better protection. H.R. 1627 does not deliver on the need to protect children. A National Academy of Sciences' report cites deficiencies in information needed to make good scientific decisions. With the release of the National Academy of Sciences' June, 1993 report, *Pesticides in the Diets of Infants and Children*, the public once again was reminded of the failure of the U.S. government to adequately protect the population from potentially harmful exposure to pesticides. While the report focuses on inadequate protection of children from pesticides, the central conclu-

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[1] Aspelin A. Pesticide industry sales and usage: 1992 and 1993 market estimates. Office of Pesticide Programs, EPA. 1994:pp.2,18.

[2] Epstein SS. Losing the war against cancer: Who's to blame and what to do about it. *International Journal of Health Services.* 1990:20(1):53.

[3] Devra Lee Davis, Senior Expert Advisor to the Assistant Secretary for Health, Department of Health and Human Services, testimony before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, October 21, 1993.

[4] Theo Colborn, Senior Fellow, World Wildlife Fund, congressional testimony before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, p. 2, October 21, 1993.

[5] Louis Guillette, Scientific Director, Biotechnologies of the Ecological, Evolutionary and Conservation Sciences Program, Interdisciplinary Center for Biotechnology Research, University of Florida (Gainesville), testimony before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, October 21, 1993.

[6] Davis JR, Brownson RC, Garcia R, Bentz BJ, Turner A. Family pesticide use and childhood brain cancer. *Arch Environmental Contam Toxicol.* 1993;24:87-92.

[7] Leiss JK, Savitz DA. Home pesticide use and childhood cancer: A case-control study. *American Journal of Public Health.* 1995;85:249-252.

[8] Angier N. A special risk for leukemia patients. *The New York Times.* November 7, 1991.

[9] Guillette, Jr LJ. Endocrine-disrupting environmental contaminants and reproduction: lessons from the study of wildlife. *Women's Health Today: Perspectives on Current Research and Clinical Practice.* Parthenon Publication Group, New York, 1994:201-207.

sion is applicable across the general population—current methods of generating exposure data and testing for pesticide toxicity do not adequately protect those who fall outside the average. In the case of children, this means that exposure data does not take into account their diet, which is disproportionately composed of particular commodities[10] and virtually ignores the limitations of and impact on developing organ systems. In addition, while the NAS report focuses on food exposure, the authors note that pesticides are not simply a food safety problem.[11] Safety is a general pesticide toxicity issue, with a need to evaluate all routes of exposure.

The report raises serious questions about government's ability to develop meaningful risk assessment models to calculate, with any kind of certainty, the real risks that pesticides present. In fact, the report indicates that the Environmental Protection Agency has very limited ability to ensure the public that there can be adequate public health protection without major changes in the way the agency does business. In testimony in the 103rd Congress, Clinton Administration officials acknowledge the inadequacies of the current regulatory system and NAS findings of the need to overhaul the regulatory requirements. Administration officials said in congressional testimony, "As acknowledged by the NAS study, full information on consumption habits for infants and children is not up-to-date."[12] There is also a lack of analysis of multiple chemical exposures, synergistic effects, and non-cancer effects.

Despite limited information, H.R. 1627, is heavily reliant on risk assessment approaches to regulating pesticides and does not attempt to address the many deficiencies outlined by the NAS report. Risk assessment is only as good as the information and assumptions that go into it. H.R. 1627's Title II—Data Collection Activities to Assure the Health of Infants and Children and Other Measures does not institute a complete program to respond to the NAS concerns about the protection of children. And while the survey information on childhood exposure to dietary residues would help us better estimate the risks to children, H.R. 1627 does not provide the much needed resources to do the job. EPA and USDA have made it abundantly clear that the resources are lacking to do the job, and proposals before Congress will cut funds significantly, thus making it even more difficult to perform these functions.

Lynn Goldman, M.D., Assistant Administrator for Prevention, Pesticides and Toxic Substances said, "The report made a variety of recommendations concerning how EPA evaluates pesticide toxicity, residue levels, and food consumption, and how this information is used in risk assessments. The Academy's recommendations, taken as a whole, present a great challenge in terms of higher standards for the quality, quantity, sensitivity, and scope of the data the Agency uses in evaluating risks from pesticides. This is a formidable challenge, but one we are prepared to meet."[13] Unfortunately, H.R. 1627 does not meet this challenge.

The NAS report is just one of many reports that raises serious questions about our knowledge of pesticides and their effect on poople.[14] The conclusion that should be drawn from NAS and other studies is that we have insufficient information needed to safely calculate the real risk of pesticides.

II. Risk-benefit analysis is not protective of public health. H.R. 1627 wrongly embraces risk-benefit analysis as a public health tool. Regulating pesticides under risk-benefit calculations is inherently flawed because of current weaknesses and resource limitations in calculating the full range of risks, costs, and benefits.

a. Risk assessment methodologies neglect consideration of real-life exposures to dangerous pesticides. Central to the discussion of risk-benefit are questions about risk assessments. The public is told that the chemicals in wide use are tested, subject to risk assessment, and found to represent an acceptable or "negligible risk." Generally, people are told that the public is exposed to trivial or trace amounts of chemicals or that their risk from exposure to a carcinogen is one in a million.

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[10] National Research Council, National Academy of Sciences, Pesticides in the Diets of Infants and Children, National Academy Press, Washington, DC., 1993, p. 184-185.

[11] NRC, p.11.

[12] Carol Browner, Administrator, EPA, Richard Rominger, Deputy Secretary, U.S. Department of Agriculture, David Kessler, Commissioner, Food and Drug Administration, testimony before joint hearing of the U.S. Senate Committee on Labor and Human Resources, and Subcommittee on Health and the Environment, Committee on Energy Commerce, U.S. House of Representatives, September 21, 1993.

[13] Lynn Goldman, M.D., Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances, EPA, testimony before Subcommittee on Environment, Energy and Natural Resources, Committee on Government Operations, U.S. House of Representatives, October 29, 1993.

[14] Jay Feldman, Executive Director, National Coalition Against the Misuse of Pesticides, congressional testimony before the Department Operations and Nutrition Subcommittee, Committee on Agriculture, U.S. House of Representatives, June 8, 1993.

There are two problems with these assertions. First, ur H.R. 1627, "negligib dietary risk" is not defined; it is unclear what exactly tl of legislation co templates as negligible. Further, in the same breath, H.. voices this, it cr ates exceptions under which even negligible risk can be ... (Title IV, Sectic 405. Tolerances and Exemptions for Pesticide Chemical Residues.) Secondly, wh drives these conclusions is a process of decision making that is commonly referre to as risk assessment. While risk assessment has attached to it a scientific my tique, the methodology brings with it some commonplace assumptions about exp sure and toxicity that the NAS report has challenged. In fact, what emerges fro any investigation of risk assessment is uncertainty, about which much has bee written. The NAS report, Risk Assessment in the Federal Government: Managin the Process (1983), concluded,

> [D]ata may be incomplete, and there is often great uncertainty in estimates of the types, probability, and magnitude of health effects associated with a chemical agent, of the economic effects of a proposed regulatory action, and of the extent of current and possible future human exposures. These problems have no immediate solutions, given the many gaps in our understanding of the causal mechanism of carcinogenesis and other health effects and in our ability to ascertain the nature or extent of the effects associated with specific exposures.[15]

The president of the American Chemical Society said, "...risk assessment r quires inferences drawn from limited scientific data."[16] A physician working in o cupational and environmental medicine, Grace Ziem, M.D., writing about multip chemical sensitivity (MCS), said, "Although initially skeptical that such illness rea tions could occur following low-level chemical exposure, I became aware that exis ing chemical exposure limits were scientifically faulty and that no-effect levels e trapolated from chronic animal studies were often orders of magnitude below cu rent legal exposure limits."[17]

b. EPA is behind schedule on reregistration. "EPA continues to fall behind i schedule to reregister the 18 major lawn care pesticides. In the meantime, the pe ticides continue to be applied in large amounts without complete knowledge of the safety. Since March 1991, EPA's scheduled study completion dates for many of t 18 major lawn care pesticides have slipped significantly, some by as much as years," according to GAO.[18] The following contributed to delays, according to GA need for higher level studies; redoing rejected studies; time extensions; and, concer about pesticide derivatives. Much of the delay seems to be a function of the re istrant failing to adequately perform a study and registrant delays resulting in tim extensions. Some delays are generated by EPA.

The same can be said for food use pesticides, most of which are also used in law care. According to testimony delivered to the subcommittee in February, 1992,

> Enactment of FIFRA '88 was intended to address such concerns [about the safety of many existing tolerances] by accelerating the reregistration of about 23,000 older pesticide products. However, the reregistration task has proven more formidable than anticipated, and EPA will not meet the 1997 reregistration time frame established by FIFRA '88. In the interim, previously registered pesticide products may be used on food under their existing registration and tolerances, despite EPA's incomplete knowledge of their human health and environmental effects.[19]

c. EPA has changed the basis of making reregistration decisions from "fully" com plete to "substantially" complete data base. Because of this change, it appears though EPA has been able to accelerate its time schedule. In the case of 2,4-D, EP eliminated the need for a crop residue study to makes its reregistration decisio saving 21 months, and decreasing the reliability of EPA's decisions and asses ments. With Isofenphos, the registrant made up 24 months in slippage when, "EP determined that it did not need spray drift studies due in 1995," according to GA

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[15] National Research Council, National Academy of Sciences, Risk Assessment in the Feder Government: Managing the Process, National Academy Press, Washington, DC., 1983, p.11.

[16] Robert Ginsburg, cited in "Quantitative Risk Assessment and the Illusion of Safety, Ne Solutions, Winter 1993, p.9.

[17] Grace Ziem, M.D., Diagnosing and Treating Chemically Injured People. Pesticides and Yo Vol.13, No.2:9-17. Also see Castleman, B.I. and Ziem, G.E. (1988). Corporate influence c threshold limit values. Am J. Ind. Med. 13:531-559; Ziem, G.E. and Castleman, B.I. (198 Threshold limit values: Historical perspective and current practices. J. Occup. Med. 31:910-91 and Roach, S.A. and Rappapert, S.M. (1990). But they are not thresholds: A critical analys of the documentation of threshold limit values. Am. J. Ind. Med. 17:727-753.

[18] GAO, April 1993, p.15.

[19] GAO, *Food Safety: Difficulties in Assessing Pesticide Risks and Benefits,* February 26, 199 GAO/T-RCED-92-33, p. 6.

"Two other pesticides, Pendimethalin and Glyphosate, improved by 28 and 12 months, respectively, since June 1992, for similar reasons."[20] EPA says it will be using data on similar pesticides when it drops a data requirement or will proceed with reregistration even though the study has not been received. According to GAO,

> One of the 18 pesticides—Glyphosate—is currently in Reregistration Eligibility Document (RED) preparation. Although EPA had earlier rejected a number of the registrant's environmental fate studies, it determined that the data base for Glyphosate was sufficiently complete with the studies. EPA officials told us that they may not require the registrants to repeat the rejected studies.[21]

EPA told GAO that it might make registration decisions without waiting for a 1996 groundwater study on Diazinon or a cancer study on a Atrazine metabolite.

d. EPA does not have adequate exposure data to make safety decisions. In its February testimony, GAO indicated that EPA did not have reliable data on the quantity of pesticides used on food crops. The statement went even further to say that inadequate knowledge supports risk estimates. According to GAO,

> Our recent work on EPA's use of USDA's Nationwide Food Consumption Survey illustrates how inadequate knowledge may affect pesticide risk estimates. To establish safe levels of pesticide residues in or on food, EPA estimates dietary exposure to pesticide residues using data from USDA's survey, which is conducted every 10 years. However, we found that EPA's estimate of potential human exposure to pesticide residues in food is uncertain because these surveys are flawed. For example, our review of USDA's 1987-88 survey found that it was not representative of the U.S. population because the response rate was too low. To compensate for this deficiency, EPA is using the older 1977-78 survey data to estimate food consumption, but his survey may not reflect the current eating habits of Americans. Moreover, neither the 1977-78, nor the 1987-88 Nationwide Food Consumption Survey sampled subpopulations, such as infants and pregnant females, in numbers large enough to permit precise estimates of their dietary exposure and, hence, of risks to them from pesticide residues.[22]

Similarly, with nondietary exposure, EPA has poor exposure data to use for purposes of reregistration because the agency simply assumed that significant exposure was unlikely. However, the agency is in the process of rethinking the low exposure assumption. "In particular, they mentioned uncertainty about the persistence of lawn care pesticides in the environment and the amount of exposure received by children who, because of greater contact with treated areas, may receive more exposure than previously thought.... EPA is working on better testing and assessment guidelines for all types of residential exposure to toxics," says GAO.[23] It appears unlikely that EPA will have guidelines developed before FY 1997, if funding becomes available. And so, one of the critical elements of implementing a meaningful reregistration standard—exposure data—is simply missing or wholly inadequate. GAO recommends that a pesticide "should not be reregisterod for lawn uses unless EPA is confident that there is no health risk from exposure, especially to children."[24]

Farmworker protection remains inadequate under new worker protection regulations that do not ensure that all workers have full information, training and medical monitoring provided all other workers protected under the Occupational Safety and Health Act. Our country's "harvest of shame" must be addressed within the context of reregistration to ensure the well-being of those who harvest the nation's food.[25]

e. Integrity of Test Data is Still an Issue. The EPA Inspector General reported to the agency in 1991 of inadequate auditing of testing laboratories used by chemical companies that generate studies used for reregistration. We are not aware of any followup action resulting from this report that would ensure the public of the integ-

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[20] GAO, April 1993, p.17.
[21] GAO, April 1993, p. 17.
[22] GAO, February 1992, p. 7.
[23] GAO, April 1993, p.26.
[24] GAO, April 1993, p. 32. GAO says, "[U]ntil the new guidelines for conducting post-application exposure studies and risk assessments are developed, EPA will not know for certain how much exposure is associated with lawn care use of pesticides and what the subsequent health risks really are, especially for children."
[25] According to the GAO, *Hired Farmworkers: Health and Well-Being at Risk* (GAO/HRD-92-46), "Hired farmworkers are not adequately protected by federal laws, regulations and programs; therefore, their health and well-being are at risk. Hired farmworkers go into fields sprayed with pesticides, but many have no knowledge of the specific chemicals they are exposed to or the potential health effects. Field sanitation on many small farms may be inadequate, constituting a serious health hazard to hired farmworkers on those farms. Young children... may be more susceptible than adults to the harmful effects of pesticides."

rity of test data used for reregistration.[26] GAO has similar concerns: "In our review of EPA's regulation of disinfectants, we found several weaknesses in EPA's data review, lab inspection, and data audit programs, which inhibited EPA's ability to ensure the quality and integrity of registrant-submitted data."[27]

f. Differences in professional judgement led the state of California, under the state's Birth Defect Prevention Act of 1984 (SB 950) to different safety findings from EPA. These issues are further clouded by differences in professional judgement. The data used to register pesticides continues to be generated by registrants. It is still not peer-reviewed, and it is still not generally available to independent scientists or the public.

g. The benefits analysis in H.R. 1627 does not consider the full cost of pesticide use. The risk-benefit analysis, as proposed in H.R. 1627, neglects to consider the full range of costs associated with the adverse public health, environmental and economic impact of pesticide use. For example, Section 102. Cancellation (B)(5)(D) requires the Secretary of Agriculture to conduct an analysis of the proposed action on the availability and price of food, as well as "associated societal impacts (including consumer nutrition and health and low-income consumers)," but does not require an evaluation of the cost of adverse effects. There is increased general understanding that pesticide use has secondary environmental and economic impacts, which some researchers have totaled at $8 billion annually.[28] Omitting these costs from the calculations prevents policy makers from making economically and environmentally sound decisions.

h. The proposal in H.R. 1627 to repeal the Delaney Clause is not based on a sound scientific and public health prevention principle. In the time since the 1992 Ninth Circuit court decision upholding the Delaney Clause, the provision has been called outdated and anachronistic by politicians and industry interests. However, the law is based on the scientific understanding that we cannot prove the level at which a cancer causing substance initiates a cancer effect, although we can determine that a chemical is a carcinogen. This distinction stems from the fact that high dose animal experimentation can tell us that a chemical causes cancer, but it does not tell us the low dose point at which the chemical has no effect. Given that carcinogens have delayed or long-term effects, animal experiments have never been able to replicate the time period and low dose. For all the criticism, the high dose method has yielded impressive results, proving accurate in the vast majority of cases where chemicals are known through epidemiological studies to cause cancer in humans.[29] There is no scientific basis for suggesting that any carcinogenic exposure represents a "trivial" or "negligible" risk. The Delaney Clause errs on the side of public health protection and rightly so.

Increases in technological capacity to detect smaller and smaller quantities (or levels) of chemicals to the part per trillion or greater does not negate the critical scientific need to establish a threshold safety level. This is the point at which an adverse effect is initiated or promoted.

Those arguing the Delaney Clause's demise would have it replaced with an undefined "negligible risk" standard, as proposed by H.R. 1627. The "negligible risk" standard is steeped in risk assessment methods that are filled with uncertainties and miscalculations as to sensitive population groups, such as children and elderly,

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[26] In the wake of major pesticide laboratory testing scandals involving falsified pesticide health and safety data, EPA's Office of the Inspector General (IG) has revealed serious gaps in the agency's Good Laboratory Practices (GLP) inspection program. According to the IG, EPA might not recognize a bad study when it came across one because, "The Agency does not have standards to determine if a specific GLP deficiency would compromise the validity of a study." According to the IG, "Of the 220,000 studies completed under FIFRA, only 2,268 have ever been audited—just under one percent." Since the program's inception, only 17 cases were pursued and penalties ranged from $1,500 to $30,000. The IG "believe[s] this low level of penalties gives the wrong message to industry—that the GLP Program is not a high priority, and no penalty, or a very small penalty, will result from not complying." When faulty or fraudulent data is identified, it does not affect the registration of the pesticide product in question. Instead, manufacturers are simply granted an extension to meet data requirements. [Kenneth A. Konz, Assistant Inspector General for Audit, memorandum to Linda Fisher, Assistant Administrator for Pesticides and Toxic Substances, EPA, "EPA's Procedures to Ensure Quality Data Under the Good Laboratory Practices Program," September 30, 1991.]

[27] GAO, February 1992, p. 13.

[28] Pimentel D, Acquay H, Biltonen J, Rice P, Silva M, Nelson J, Lipner V, Giordano S, Horowitz A, D'Amore M. Environmental and economic costs of pesticide use: An assessment based on currently available U.S. data, although incomplete, tallies $8 billion in annual costs. *BioScience.* 1992;42(10):750-760.

[29] Wilbourn, J et al., "Response of experimental animals to human carcinogens: an analysis based upon the IARC Monographs programme," *Carcinogenesis,* vol. 7, no. 11, pp. 1853-1863.

average body weight, consumption patterns, and other exposures affecting the total toxic load that any one individual already carries.

H.R. 1627 does not address: multiple chemical exposure through dietary and nondietary exposure; limitations of the negligible risk standard to quantitatively define carcinogenic risk; deficiencies in estimating cancer potency; and non-cancer risks, such as endocrine system disruption.

- *Risk assessment models are not accurate.* Many theoretical dose-response models of carcinogenesis have been proposed, each of which leads to a particular mathematic form of the dose-response relationship.
- *Testing methodology makes low dose effect level impossible.* Risk assessment is based upon two assumptions: First, extrapolation of the experimental results of tests performed at high exposure or dose levels to much lower exposures in animals. And second, extrapolation of these estimated risks for low doses in animals to risks for humans at comparable doses.

This further assumes that humans will not be more sensitive to a particular carcinogen than animals. And that chemicals that do not cause cancer in animals also would not do so in humans. These assumptions simply are not so.

Nevertheless, the scientific community has generally endorsed the maximum tolerated dose (MTD) approach to testing for carcinogenicity in animals, which is then extrapolated to humans. The MTD approach has been endorsed for purely practical reasons. According to *Issues in Risk Assessment* (1993), "[T]ests conducted at lower doses will probably have little power to detect carcinogenic effects, unless the number of animals tested is increased immensely, which would increase the cost of a bioassay commensurately; the large number of animals required for detection of the smaller increase in tumors incidence that might occur at low doses is one of the primary reasons for use of the MTD in carcinogenicity bioassays."[30]

- *Variations exist in susceptibility of humans to cancer.* Both human data and the results of animal experiments tell us that individuals vary greatly in their susceptibility to the effects of carcinogens. But we do not know how to identify those most at risk.[31] Not all exposed people develop cancer, suggesting a considerable variation in susceptibility to carcinogens (which might or might not have something to do with genetics). Not everyone exposed to materials containing hydrocarbons develops skin cancer. Not everyone who smokes develops lung cancer. Not everyone who worked with 2-naphthalamine or benzidine developed cancer of the urinary bladder.

The dilemma is that we cannot prevent exposure to all foreign chemicals. And yet we do not have adequate methods of determining which chemicals are carcinogenic and which are 'safe.' Therefore, it is unwise for anyone to predict how many cases of cancer will result from exposure of people to a particular amount of carcinogen.

- *It is impossible to determine safe threshold levels of exposure.* A National Academy of Sciences committee on saccharin stated: "All theoretical dose-response models have one thing in common, that there is no known uniform threshold dose below which any carcinogenic response is impossible for all individuals at risk. Even if thresholds do actually exist, it is scientifically impossible to measure them or to prove their existence."[32]

It is not possible to conduct plausible experiments which enable us to establish a safe threshold for exposure of people to any carcinogen revealed through experiments in animals. Few dose-response studies over a large range of doses have been carried out and in those, mainly with nitrosamines, there have been significant cancer responses even at the lowest doses used, which were lower than those to which workers in some occupations are exposed.[33]

- *A No-Observable Effect Level (NOEL) can not be established.* The most difficult aspect of carcinogenic risk assessment is the establishment of a No-Observable Effect Level (NOEL) in experimental animals. According to Lijinsky, several much studied nitrosamines—diethylnitrosamine, dimethylnitrosamine and nitrosomorpholine—have shown a "significant carcinogenic effect after administration of doses to rats totalling less than 1 milligram during their lifetime, or less than 5 milligrams per kilogram body weight. This equates to a third of a gram for a human and is *above the no-effect level. No tolerable or 'de minimus'*

[30] National Research Council, National Academy of Sciences, Issues in Risk Assessment, National Academy Press, Washington, DC., 1993, p.5.

[31] Lijinsky, W. U.S. Health will be Jeopardized if Delaney Clause is Abandoned. *Chemical & Engineering News*, June 27, pp. 25-28, 1977.

[32] Committee for a Study on Saccharin and Food Safety Policy. National Research Council, National Academy of Sciences. Saccharin: Technical Assessment of Risks and Benefits. Washington, DC., November, 1978.

[33] Lijinsky, W. et al. A dose-response carcinogenesis study of nitrosomorpholine in F344 rates. *Cancer Res.* 48:2089-2095. 1989.

dose could be established for such a carcinogen. Nor can such an exercise be meaningful for any carcinogen without impossibly large and expensive experiments in animals, or in the absence of deliberate experiments in humans."[34]

- *Real life situations are not considered.* A further argument against the use of threshold models for the estimation of attributable risk is that the environment contains many carcinogenic agents and that the particular chemical in question may be acting not only additively, but also synergistically, over and above the background. We do know that pesticides, particularly organophosphates, act synergistically with each other and with other types of pesticides.
- *Exposure to multiple pesticide residues is a reality.* An individual product may not pose more than a 'negligible risk'; however, exposure to numerous foods with pesticide residues will increase the toxic body burden substantially. A compreliensive calculation of the risk from eating a particular product with residues of multiple pesticides is not as dangerous as the risk from eating multiple commodities, which together present a higher risk.
- *Synergism of pesticides is not considered.* Synergism, or potentiation, involves situations in which the joint effect of two or more agents is greater than the sum of their individual effects. Interactions may occur in mixtures, substances with more than one component. Pesticide formulations themselves are usually complex mixtures. Multiple pesticide residues in food are mixtures of substances left over from agricultural treatments. The problem of detecting interactions is complex because of the enormous number of chemicals and combinations to which exposures may occur.
- *Extrapolation from test animals to humans is the current practice.* Using animal evidence of carcinogenicity to ban human food additives actually underestimates the problem. As mentioned previously, humans may well be more sensitive to a carcinogen than animals. Equally important, however, is that humans are exposed to many carcinogens rather than just one carcinogen, as animals are exposed to in lab tests. Unlike the rat that is exposed to a single carcinogen, a human may get drugs, air, water, and occupational exposure laced with carcinogens, to say nothing of other food additives that may not yet have been tested to see if they cause cancer. A little bit of this plus a little bit of that seems to be, at the least, additive and, at worst, synergistic.
- *Other factors to consider.* As noted above, risk assessments also need to take into consideration special groups, such as children, pregnant women or the elderly. Because of the special sensitivity of the fetus and small children to carcinogens, it is most important to avoid exposing children and pregnant women to pesticides.

The young generally are more susceptible to chemical poisoning because of their lower levels of detoxifying enzymes and the elderly are also more sensitive. Humans suffering from liver, kidney or central nervous system disease should not come into contact with pesticides. Persons with preexisting illnesses, such as allergies, emphysema, asthma, glaucoma or cardiovascular diseases should not be exposed to dangerous chemicals.

- *Conservative Risk Assessment Models are Crude.* Depending on the assumptions and models that are used, it has been found that calculated risks can vary by orders of magnitude. Even conservative models may not be as conservative as commonly believed. The one-hit model, which is the popular risk assessment model widely considered to be 'conservative,' is used by the EPA:

The One-Hit Model assumes that a single exposure to a carcinogen may cause cancer. It is accepted practice to rely on animal cancer bioassays in which animals are exposed at doses that approximate the animal's maximal tolerated dose. The positive dose is used to predict or generate a graphical dose-response curve. The shape of such a curve may vary from chemical to chemical and even for a single chemical is not likely to be linear over its entire range. Cancer incidence is plotted against dose of the carcinogen by plotting data points relevant to the high end of the curve, where doses are high. The validity of extrapolation down to low doses is not easily verifiable, and may not accurately predict the shape of the curve at that end of the scale.

- *Public Availability of Data is Limited.* Often there is only one manufacturer of a pesticide. Therefore all acute and chronic toxicity, carcinogenicity, teratogenicity and mutagenicity studies used to register the pesticide have been generated in the past and still continue to be generated by the manufacturer. These studies have been claimed by the manufacturer to be proprietary and trade secret and therefore have not been published or otherwise made available

[34] Comments of William Lijinsky on "Correction of Listing of D and C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics." *Federal Register* 52:5081, February 19, 1987.

to the scientific community for peer review. This will continue to be the case under H.R. 1627. (Title III, Section 301-303.) It is generally accepted in the scientific community that published, peer-reviewed toxicology and pathology studies are the only reliable evidence on which to base the toxic effects of chemical compounds.

EPA's scientists, manufacturer's scientists, or for that matter anybody's scientists, should not have total control over the scientific or other data and its interpretation. The data have not been and still are not generally available to independent scientists or interested members of the public. The Freedom of Information process is plagued by long delays and deliberations with industry over the confidentiality of basic health and safety studies.

Health and safety testing data should not be confidential. Data confidentiality prohibits public discussion and debate. Companies should not be allowed to make public 'data summaries' and prevent meaningful public examination of the basis for their interpretations.

- *EPA and other governments and industry mislead the public.* EPA has insisted that it does not 'approve' pesticides, but simply 'registers' them. The Food Marketing Institute, along with FDA, made the following incorrect statement: "Before a pesticide is approved for use, the EPA requires extensive testing and safety studies to demonstrate that the product works as intended and won't pose unreasonable risks to people or the environment."[35]

GAO, in 1986, concluded that "The public receives misleading information on pesticide hazards."[36] Trade groups and states, with the cooperation of federal agencies, have confused rather than informed the public by misinterpreting the facts. Risk issues will continue to be distorted by both industry and government under H.R. 1627. EPA often makes the blanket statement that the likelihood of carcinogenic effects in humans from exposure to low levels of pesticides is nonexistent or extremely low. A statement like this ought not be made in the face of the paucity of information.

- *Secrecy of product ingredients undermines public oversight, independent analysis and consumer right-to-know.* All ingredients in pesticide product formulations and resulting chemical residues on food commodities should be disclosed to the public. From a public safety standpoint, the public (both users of pesticides and consumers of food) has a need to know what chemicals are contained in the pesticide products to which it is exposed.

III. State and local authority to exceed federal standards is essential to good public policy on health and safety and democratic ideals. H.R. 1627 betrays the basic principle of states' rights.

Preemption is undemocratic and unacceptable policy and attacks states' rights. The authority of states to protect residents is essential to decision making in a democracy. It is especially important given the flexibility provided the regulatory agency to engage in risk assessment decision making, with a range of possible assumptions and population groups. H.R. 1627 takes away state authority to set tolerances [Sec 305, amends 408(l)]. This is wrong. Federal food safety law, whatever it ultimately looks like, should establish a minimum standard of public health protection. We believe it is inappropriate for the federal government to lock states out of the process of protecting their residents in a manner that is more protective than the federal government. Citizens have a right to act at the state level to protect themselves, their families, and their communities. A provision in H.R. 1627 to create "uniformity," and thus lock states out of the process of setting tolerances when they determine the need, runs contrary to a long-established relationship between the federal government and the states.

We are faced with a federal regulatory system that is failing the American public. EPA has been engaged in a series of controversial risk and cancer classification decisions for the past decade. The public should not have to depend on a system of decision making that has failed to meet its statutory duty to evaluate pesticides, protect public health and the environment, and then deny states their basic right to protect the health and welfare of their residents. Pesticide policy has governed a system that has been plagued by inaction and inappropriate action in our view.

Given this situation, it would be counterpreductive to prohibit states from involving themselves in the difficult task of safety decisions. Historically, states have

[35] Food Marketing Institute in cooperation with the Food and Drug Administration (FDA). undated. A Consumer Guide to Food Quality and Safe Handling: Produce and Pesticides. Washington, DC.

[36] GAO. 1986. Nonagricultural Pesticides: Risks and Regulation. Washington, DC., GAO/RCED-86-97.

played a very constructive role in setting standards and contributing to EPA's dec sion making process, as a result.

Instead of quashing states rights, legislation should seek to make states partner in an effort to address the serious national problem of pesticide contamination. Fo instance, if we are serious about better understanding of and attention to the pes ticide problem, our country needs a national and state partnership for recording and evaluating overall chemical use and associated adverse effects. What goes on at the local and state level is important to EPA, but where there is federal inaction, states must be able to act. In fact, important information does not always make it to the federal level, as witnessed by EPA's $732,000 fine against DowElanco in early May, 1995 for its failure to report pesticide incidents. The company's report of 249 incidents associated with the widely used insecticide, chlorpyrifos (Dursban) came well after the required 30-day time period and only after a television news broadcast was scheduled to disclose many of the cases.

Similarly, efforts in H.R. 1627 aimed at harmonizing safety standards with the international Codex standard takes the concept of preemption to the international arena and should be rejected. United States sovereignty to determine its health and safety standards unimpeded should be a basic tenet in all U.S. laws.

IV. Conclusion. Our positions are presented to the subcommittee in the context of experiences from the grassroots on a daily basis. Our positions do not represent political posturing. Nor do they represent a view that promotes an economic self-interest. In fact, the positions NCAMP advocates grow out of the thousands of people, urban and rural, farm and non-farm, that contact the organization in search of answers to questions about pesticide poisoning and property damage or in an effort to prevent such ill-effects. What is most encouraging is that we not only hear about how our federal regulatory system has failed to protect public health and the environment, but we hear about the resourcefulness of those putting alternative pest management systems in place—systems that do not rely on pesticides.

There are numerous model pest management systems for farms, structures and landscapes. In agriculture, there are many highly successful sustainable agricultural systems that reduce pesticide dependency.[37] Organic agriculture has shown itself to be profitable and productive. Soybean growers in Practical Farmers of Iowa have replaced the cancer causing herbicide alachlor with tillage systems and planting techniques to shade out weeds. They eliminated one of the 32 carcinogenic pesticides announced by EPA while maintaining productivity and profitability—at yields higher than the state average and an average savings of at least $11.00 an acre.[38] In schools, parks, along rights-of way and in forestry, alternatives to pesticides have proved successful. The Government Services Administration, in its pest control program for 30 million square feet of federal office building space, has reduced pesticide use by 98 percent, through the use of integrated pest management.[39]

Our country's pest management systems must be reoriented toward pest prevention, by designing out vulnerabilities and stress in the agricultural environment and practices in the urban environment that invite pest problems. Until we are able to do this, we will maintain our current crisis orientation toward pest management with an exaggerated need for pesticide use and pressure to accept higher and higher risks because of escalating pest problems.[40]

Legislation can either help us move down the path to ecological and environmentally sound alternatives or hinder our progress by sending us down the toxic chemical path. The question that we face as a nation is how to achieve our pest management needs without an unnecessary reliance on toxic inputs. We must evaluate legislative proposals in this context. H.R. 1627 takes us down the toxic chemical path, promoting continued reliance on hazardous materials that are so often not needed.

We look forward to working with the Subcommittee during your deliberations on H.R. 1627 and expect to see a robust public interest in the outcome of these proceedings. Thank you.

Mr. BILIRAKIS. Thank you, Mr. Feldman.

Ms. Brickey.

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[37] Board on Agriculture, National Research Council. Alternative Agriculture. National Academy Press. 1989.

[38] Practical Farmers of Iowa. Weed Control Trials. Ames, IA: Practical Farmers of Iowa. 198

[39] Greene A. Integrated pest management for buildings. *Pesticides and You.* 1993:13(2):18-2

[40] Shistar T, Cooper S, Feldman J. Unnecessary Risks: The Benefit Side of the Pesticide Risk Benefit Equation. National Coalition Against the Misuse of Pesticides. 1992.

STATEMENT OF CAROLYN BRICKEY

Ms. BRICKEY. Thank you, Mr. Chairman. It's a pleasure to be here today representing the National Campaign for Pesticide Policy Reform which is a coalition of about 60 groups throughout the country who support the implementation of new pesticide policies.

One point I would like to make at the outset is that I believe that some of us participating in this hearing today are probably coming from different assumptions about the law. I think that perhaps some members of the committee and certainly some of the organizations supporting H.R. 1627 believe that the current law is adequate to protect the public health except the Delaney Clause is too strict.

I and some of the others who are participating in the hearing believe the law is not strict enough as it is and that we need to make some changes in the law to make it work better. Certainly we have had report after report done by the GAO and others that tell us that the law is broken and needs to be fixed, and I refer specifically when I say that to the FIFRA provisions of the law which are being considered by the Agriculture Committee.

I believe the test for this bill as the committee considers it ought to be whether or not the food supply is safer and children are better protected if this bill is enacted. Based on my analysis of the bill, I would have to say no to both of those questions.

For many years a number of parties have advocated the replacement of the Delaney Clause with a new standard that would apply to both raw and processed food, but the question has always been, what should that standard be? Mr. Chairman, the devil is always in the details, and we have heard extensive discussion today about the difficulty of defining negligible risk, for example, in the context of looking at noncancer effects.

I also believe there is difficulty in defining negligible risk at some level on the part of EPA if the law does not provide more stringent requirements than it does here. I believe this rendition of negligible risk can be interpreted very loosely and weakly by the EPA, and that we would find it to be a step backward in the law.

The settlement in *California* v. *Browner,* which of course is based on the implementation of the Delaney Clause, provides for rapid examination and an orderly phaseout of a number of pesticides that also may cause other health risks besides cancer. Many of these pesticides we would consider to be priority pesticides that EPA should be looking at some time ago in the reregistration process. I would not agree that these pesticides constitute a risk to the food supply until EPA has fully evaluated them and made some decisions.

What would happen, if this bill is enacted, to the chemicals that are named in this settlement? I believe that many of them could remain on the market indefinitely even if they are probable carcinogens already classified by EPA, and I think that would be a bad result for the public health.

The bill attempts to amend 30-odd years of law in the FFDCA, and the result will be more carcinogens in the food. We can argue about the strength or weakness or potency of each one of those carcinogens, but there is no doubt that cumulatively that is what would happen. It is also unclear how this new standard would be

applied to noncancer health effects, as has been discussed extensively here today.

I also believe that the bill does fail to adequately protect children. I think there are a number of roadblocks to protecting children that Erik and others have mentioned, but I also believe that there needs to be clear and articulated standards in the law that would require the implementation of the NAS report. Instead, this bill does not require a specific finding that a pesticide be safe for children nor does it require that the specific recommendations of the NAS report be implemented. I think that is a problem.

I also believe that pesticide exposure could be reduced or avoided if safer alternatives are adopted by farmers. I believe that as a policy this Congress should do everything it can to further that goal and make it happen. How can we bring new products and new technologies on to the marketplace if we keep all the old technologies out there if all the old products—which, frankly, in many cases are much cheaper, I can understand the economics of this for farmers—but how are we going to get the newer, safer technologies on the market if we keep all the old products in the status quo?

That is the issue, I think the most important policy issue facing this Congress that this committee needs to examine very carefully, and I would urge you to cooperate with the Agriculture Committee to do everything possible to further the development and the dissemination of new technologies and off-the-shelf technologies that may already be available that farmers could be using and give farmers the opportunity to promote a safer, higher quality food supply than the one we have now.

Thank you.

[The prepared statement of Carolyn Brickey follows:]

PREPARED STATEMENT OF CAROLYN BRICKEY, EXECUTIVE DIRECTOR, THE NATIONAL CAMPAIGN FOR PESTICIDE POLICY REFORM

Mr. Chairman, and distinguished members of the Committee, thank you for the opportunity to testify today on HR 1627, the *Food Quality Protection Act of 1995.*

I am Carolyn Brickey, Executive Director of the National Campaign for Pesticide Policy Reform. The National Campaign is composed of a coalition of 60 organizations—consumer, environmental, health, women's, and others—throughout the country.

Attached to my written statement which I request be inserted in the record is a list of our members.

The Campaign favors basic reforms to the pesticide laws. First, the most toxic pesticides which may cause cancer, birth defects, neurological damage or other problems should be phased out of use as quickly and expeditiously as possible. Second, children should be protected from harmful pesticide exposures. A key way to meet this goal is to implement the National Academy of Sciences report, "Pesticides in the Diets of Infants and Children." Third, farmers must receive the proper instruction and incentives to use new pest control technologies that are non-chemical, wherever feasible. Technology transfer is critically important, and the U.S. Department of Agriculture should be in the forefront of development and dissemination of new technologies.

When it comes to reforming pesticide policy, it seems like a very long and winding road to me. I have been a part of two legislative efforts—one successful and one unsuccessful—to try to change the way the law works to make it better.

The unsuccessful effort in 1986 represented an attempt to develop consensus between public interest groups and the chemical industry. The successful effort in 1988 consisted of changes to the law to eliminate a few of its most antiquated features and to give EPA the resources to reevaluate hundreds of older pesticide ingredients—many of which do not meet today's health and safety standards.

This testimony focuses on proposed amendments to the Food, Drug and Cosmetic Act, but the Campaign also is concerned with the amendments to the Federal Insec-

ticide, Fungicide and Rodenticide Act (FIFRA) and the minor use provisions of the bill which are being considered by the House Agriculture Committee.

All along the program has been hampered by many weaknesses and by a lack of resources to get the job done. The problems associated with pesticide use illustrate these shortcomings. The program operates on a treadmill through which the same health and safety issues are revisited time and time again with little resolution or clarity to protect public health. For example, once a serious health question is raised, it may take 7 or 8 years—or even longer—to get a decision about the pesticide.

This was true even before the National Academy of Sciences (NAS) report—*Pesticides in the Diet of Infants and Children*—was issued in 1993. The report represents a straightforward evaluation of a regulatory system seriously out of sync. The distinguished and diverse Academy committee characterized the pesticide tolerance system as inadequate to protect children and prescribed a series of steps to make it more protective. To date, EPA has been working administratively to incorporate some of these recommendations, but much more needs to be done.

A study conducted by the Environmental Working Group (EWG), *Pesticides in Children's Food,* documented for the first time the prevalence of multiple residues in single foods, and showed that it is not uncommon for children to eat single pieces of fruits or vegetables with 5 or more pesticides on them. This study provided documentation of the Academy's report and pinpointed one of the major defects in current pesticide law—EPA regulates pesticides as though people are exposed to them one at a time.

This study illustrated the severity and imbalance of pesticide exposure early in life, showing that up to 35 percent of lifetime exposure to some carcinogenic pesticides occurs by age 5. The risk is a result of disproportionately heavy early exposure to eight carcinogenic pesticides routinely found in just 20 fruits and vegetables. The average child could exceed EPA's "acceptable" lifetime level of risk by age one.

A subsequent EWG study, Washed, Peeled—Contaminated, showed that even food that had been processed for consumption contained multiple pesticide residues, thus refuting the common adage that you can wash pesticides off your food.

Today, this Committee is examining the provisions of H.R. 1627, and it is the Campaign's position that the Committee should find this bill seriously lacking.

HR 1627 does not implement the NAS Committee's recommendations and does not guarantee protection for children. We therefore strongly oppose its enactment.

- It does not require specific protection for children.
- It does not ensure that exposure to pesticides at legal limits is safe for children.
- In fact, HR 1627 does not implement a single finding of the NAS Committee report that requires EPA to change the way that tolerances are established; it does not require an assessment of exposure from all sources, as recommended by the Academy panel, nor does it include any special methodologies or safety factors to protect children, as recommended by the NAS panel.

Instead, we support provisions to effectively implement the Academy's report to the fullest extent possible, including the development of special methodologies and safety factors that protect children from all routes of pesticide exposures. Because of multiple exposures on food and from other sources, many children reach lifetime exposure levels before the age of 5 or even by age one.

In its consensus report, National Academy of Sciences committee on pesticides in the diets of infants and children found the entire pesticide tolerance and regulatory system lacking, and particularly inadequate to protect young children. The Academy concluded that "tolerances are not based primarily on health considerations" and that "the current regulatory system does not specifically consider infants and children." To address these failings, the committee recommended "that EPA modify its decision making process for setting tolerances so that it is based more on health considerations than on agricultural practices," and that specific changes be made to protect young children.

The committee made clear that children need special protection from pesticide residues in food. Specifically, the committee recommended that "in the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children." To account for this likely increased sensitivity the committee urged that "the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity *and when data from toxicity testing relative to children are incomplete.*" In addition, the committee cited the common occurrence of simultaneous exposures to different pesticides with the same toxic effect, and recommended accounting for multiple exposure in regulatory risk assessments.

Finally, the NAS committee left no doubt about the basic goal of pesticide regulation as it relates to food residues: "Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins. This goal should be kept clear."

HR 1627 does nothing to change the current paradigm of continuing pesticide use.

The current pesticide regulatory system is built on the notion of maximum acceptable risk. The goal is not to produce abundant and affordable food using the least amount of pesticides possible; rather it is to set and allow maximum acceptable levels of human and environmental exposure to hundreds of pesticides in thousands of formulated pesticide products applied to hundreds of food and feed crops. The foundation of this paradigm is the untenable notion that scientists and regulators can accurately assess the risks from residues of 20,000 different formulated pesticide products all interacting in the environment and the human body.

Not only is the basis of this process highly implausible, it is extremely expensive. It provides no incentives for agricultural production innovation, and allows maximum opportunities for delay. It is extremely bureaucratic, unpredictable, founded on misplaced burdens of proof, and divorced from market forces. It captures all of the bad elements of failed regulatory policies in other areas. It can be rightly characterized as "end of the pipe" regulation for food.

HR 1627 enshrines into law all of the negative features of current policies.

Nothing is done to assist or encourage farmers to adopt new technologies that could promote safe food and water, as well as reduce farmers and their workers' exposure to many hazardous pesticides. Indeed, HR 1627 continues down the current negative track that threatens workers, consumers and our environment. Beyond its general flaws, we oppose HR 1627 for many specific reasons. Some of the most important are as follows:

HR 1627 is a poor bargain for the public health.

HR 1627 repeals the Delaney Clause of the Federal Food Drug and Cosmetic Act, the most protective preventive public health standard in federal law. It is replaced with the weak, ineffective, and entirely subjective risk benefit standard currently contained in FIFRA. This standard has proven over at least three decades to be crippled and ineffective. The staggering number of years it take's EPA to act on any single pesticide health threat well illustrates this point. It makes much more sense to enact a strong health-based standard that protects the public and processed food than to replace a strong standard with a new weak one such as the one proposed in H.R. 1627.

HR 1627 codifies in law the current regulatory bias toward agricultural benefits, and fails to acknowledge the need for greater protection of the public health, as recommended by the NAS committee report. HR 1627 specifically allows economic benefits to farmers to justify public health risks in excess of the level determined as negligible by the EPA. In other words, the bill establishes a negligible risk standard and immediately provides a major loophole to it.

HR 1627 does nothing to reduce the use of pesticides.

On June 25, 1993, the Clinton Administration announced an historic shift in pesticide policy, declaring a commitment to pesticide use reduction and the promotion of sustainable agriculture. HR 1627 does nothing to advance this goal. Why not help farmers get off the pesticide treadmill instead of encouraging the status quo?

HR 1627 weakens currently inadequate standards for food tolerances.

The EPA currently establishes food tolerances by adding up the risks presented by all food uses of a pesticide. HR 1627 appears to weaken this standard by requiring that exposure calculations be reduced to a single pesticide on a single food. HR 1627 further does not respond to the recommendations of the NAS committee to include all routes of exposure (food, water, garden, and home applications) in the establishment of food tolerances.

HR 1627 removes state authority to set pesticide residue tolerances to protect the public health.

In this case "uniformity" may mean weaker standards. Former EPA Administrator William Reilly called the states "laboratories for innovation." When state government decides to exercise its authority to protects its citizens, why does it have to come back to the federal government to ask its permission? Why are states' rights valid to weaken the law, as is being promoted in other circumstances, yet cannot be used to strengthen public health protection in this case? It appears to be a major

contradiction. This power has been seldom used, but it is an important added protection that should not be taken away.

A New Policy is Needed to Reduce Pesticide Use and Promote Sustainability.

All food production and pesticide regulatory policies should work coherently toward the same goal: producing food with the least amount of pesticides possible, and where appropriate and reasonable, no pesticides at all. This goal should be accomplished at the least cost to taxpayers, consumers, and farmers.

Many farmers have already phased out or eliminated their use of pesticides. They say that virtually any food can be grown without pesticides. They believe their health and that of their families justified the change in their farming practices which has also resulted in safer, higher quality food.

Within this framework, certain specific policy changes must be made.

- Pesticides that pose unacceptable risks to children and other high risk populations must be phased out.
- Pesticides that remain on the market must meet strict health-based criteria designed specifically to protect children and other sensitive or highly exposed groups.
- USDA must embark on an initiative to provide pest control alternatives to growers of crops most dependent on pesticides that present the greatest risks to human health and the environment.
- Consistent and enforceable market incentives that reward growers for reduced and low pesticide use must be established.

HR 1627 accomplishes none of these goals, and erects significant obstacles to their achievement. We therefore strongly oppose its enactment.

Mr. BILIRAKIS. Thank you very much, Ms. Brickey.

Mr. Vroom.

STATEMENT OF JAY J. VROOM

Mr. VROOM. Thank you, Mr. Chairman.

I'm pleased to join my fellow environmental interest groups here in this final panel. I would like to point out that, in my role of representative of the manufacturers of crop protection materials, that we indeed have an interest in serving not only the interest in growing food but also we have discovered, as the marketplace has signaled over the years, that there is money to be made in serving the interests of society and better protecting the environment and providing greater assurances of protection of public health.

I would observe that there is precious little left to say in support of H.R. 1627 so might I just say dittos or perhaps even mega-dittos.

With regard to some other items that have been discussed throughout the course of the hearing here today, I heard a lot of conversation about the so-called court settlement between NRDC and the agency with regard to the big Delaney lawsuit. I think Mr. Burr in particular raised that question earlier. The simple answer is that the reason that the agency chose to accept that settlement and go to court and get the court to agree to that settlement is that they expected further litigation and this was an easy way to avoid having to make tough decisions, and, in fact, put yourself in the place of the agency regulators today. They are by nature risk averse and would like to transfer risk decisionmaking somewhere else.

We go to the question of why no answer on the NFPA petition. Again, it is because NRDC would sue them if they gave a logical answer. It will be very interesting to see what kind of answer the agency does give on the deadline this Friday to the NFPA petition. However, instead of answering the NFPA petition in a logical and science-based manner which they could do and be sued by NRDC, my industry and the owners and registrants of the products that

will be threatened to be taken off the market will be forced to litigate each and every one of those tolerance revocations. Which is a better choice and use of Government resources? Being sued by NRDC and other plaintiffs or being sued by dozens of manufacturers of crop protection products? I think the answer to that question is, pass H.R. 1627, put Delaney behind us.

It was also noted earlier a problem that is articulated around the issue of the NFPA petition—the ability of regulatory agencies to never get around to answering that kind of a regulatory process petition decisionmaking authority—and I think that speaks volumes in terms of the need to maintain the aspects of the Administrative Procedures Act in this title and other titles of this bill related to FIFRA, which has also been discussed here earlier today.

I think at issue before this committee is both the science-based regulation of crop protection products that are currently on the market and available for use in American agriculture today as well as the development and future of creative, newer, better products for tomorrow.

Today, with new crop protection product discovery to market time lines taking up to 10 years or more, the year 2050 and its 11 billion population of the world is but a hop, skip, and a jump away. I believe that H.R. 1627 will set the framework for my industry and all of agriculture to continue to invest to meet the enormous challenge of feeding the world today and in the future. A world, a hungry world, Mr. Chairman, is watching and applauding your leadership.

Thank you very much.

[The prepared statement of Jay J. Vroom follows:]

PREPARED STATEMENT OF JAY J. VROOM, PRESIDENT, AMERICAN CROP PROTECTION ASSOCIATION

Mr. Chairman and members of the Subcommittee: Thank you, on behalf of the members of the American Crop Protection Association (ACPA), for the opportunity to register our support for the extensive improvements in our food safety laws offered in the new H.R. 1627, "The Food Quality Protection Act of 1995." The American Crop Protection Association is the not-for-profit industry association of U.S. manufacturers, formulators and distributors of agricultural crop protection products. Membership is composed of companies which produce, distribute and sell virtually all of the active compounds used in crop protection in the United States.

For the past four years, ACPA has joined with scores of other food and agricultural interests—at national, state and regional levels—in support of such reform of our pesticide and food safety laws. Many of these groups are active in the 200-plus-member Food Chain Coalition.

Last session, 224 Members of the House of Representatives cosponsored similar reform legislation, along with 25 sponsors in the Senate of a parallel approach.

The new bill has been continuously honed and refined—based on input from congressional, regulatory, agricultural and environmental sources—to further reflect realistic reform measures to enhance our nation's food safety needs. We believe that the time to act is now.

The new bill is simple but not simplistic, a long delayed strengthening of the nation's premier food safety law. At the heart of H.R. 1627 is reform of the regulatory approach, allowing modem science to be applied to the establishment of pesticide residues; of implementing a single negligible risk standard for both raw and processed foods, as recommended by the National Academy of Sciences in its landmark 1987 report, *Regulating Pesticides in Foods—The Delaney Paradox.*

As the National Academy did almost a decade ago, the new law calls for modern science to be applied sensibly—and strictly—to assure that pesticide tolerances must be adequate to protect public health. In particular, the law "directs that tolerances must adequately safeguard the health of infants and children." For too long, the recommendation of the nation's most prestigious scientific organization has gone

unheeded. It is time to redress this situation; time to implement a science-based standard to assure that only the most up-to-date methods undergird our food supply.

Numerous scientific, agricultural, food processing, health, medical and nutrition groups agree that the time is now to modernize Delaney. EPA Administrator Browner, herself, has stressed the need for improvement, as have many of the nation's leading newspapers. For instance, in its May 26 editorial "Zero-Risk non Science," *the Sacramento Bee* said about the Delaney Clause, in part"...The strict standard does not reflect modern scientific understanding about what kind of residues humans can safely tolerate. In many cases, it places a huge burden on growers and processors while providing little health benefit to consumers."

The *Bee* recommends that the law be made to "...conform to what we've learned about human tolerances of pesticides—not an arbitrary standard pegged to what we did not know almost 40 years ago."

Delaney Reform is Essential

Passage of this new legislation has become even more important—and more urgent—in this session of Congress because, under court order, the EPA has been mandated to strictly interpret the Delaney Clause, even though the court acknowledged that its rigid, zero-standard may be out of date and called upon Congress to reform the law. As a result of the court's decision, EPA will soon begin to revoke tolerances for uses on approximately 100 crops of some 37 pesticide products beneficial to their production.

According to such leading experts as Leonard Gianessi, of the Center for Food and Agricultural Policy, who have examined the issue and from whom you will hear today, this is certain to drive up producer and consumer costs, decrease yield and quality of fruit and vegetable crops, and increase U.S. consumer dependence on imported food.

Protection of Infants and Children

Two years ago, the National Academy of Science, in its *Pesticides in the Diets of Infants and Children"* study, outlined a number of recommendations regarding food safety and pesticide tolerance. ACPA takes this report seriously, and so does H.R. 1627.

The Food Quality protection Act of 1995 provides even further attention to infants and children, as well as other sensitive subgroups in our population, as recommended by the NAS.

H.R. 1627 directs EPA to address areas where data on these subgroups are lacking or where current testing is inadequate to address dietary exposure to pesticide residues. At the same time, the bill allows flexibility so that EPA can use the latest scientific expertise in its deliberations, rather than be locked in to legislation which codifies science, and soon becomes obsolete—such as we've found with the Delaney Clause.

American consumers demand (and have come to take for granted) safe, affordable, abundant supplies of a wide variety of food, all year round. With the most innovative, productive farmers and food production system in the world, they are assured of that bounty every time they step into their local supermarkets. And it costs us, on average, only about 10 percent of our disposable incomes, far less than most any other people pay. Since 1900, the percentage of U.S. income spent on food purchases has dropped by 50 percent.

There has been a corresponding increase in life expectancy over the same period, from a little more than 50 years at the turn of the century to well into the late 70s nowadays. In *Pesticides in the Diets of Infants and Children*, the National Academy of Sciences attributes in part such improvements in public health to pesticides. Since the inception of modern crop protection technology in the 1940s, crop variety, yields, availability and affordability, especially of fruits and vegetables, have increased dramatically. This is why we call today for reform. For modern science. For a stronger food safety law that "...by regulation sets forth factors and methods, including tests which are appropriate for the determination of dietary risk and most likely exposure, for the determination of negligible dietary risk."

Pesticide Benefits

The issue in the legislative debate involving benefits does not question whether the use of pesticides *has* benefits, for it certainly does—but rather how data on pesticide benefits should be used to determine acceptability of any potential risks, how one product should be used to determine acceptability of any potential risks, how one product should be evaluated vis-a-vis another, and how one product compares with another technology.

As part of the registration process, current law properly provides for the evaluation of the risks *and* benefits of a pesticide. H.R. 1627 continues that provision, an inclusion which we wholeheartedly endorse. A fair evaluation of any risk must include an assessment of the benefit to be derived from risk acceptance and management. Ignoring benefits places decision-makers with "one arm behind their backs" in that the decision is put out of context, and the true understanding of risk is distorted.

ACPA, along with the Food Chain Coalition, supports the principles for evaluating the risks and benefits of pesticide residues contained in H.R. 1627. The approach is fair to registrants, protects consumers and recognizes that reasoned, informed decisions must be made with full awareness of both benefit and risk.

Even so, this provision could be improved by clear articulation of the kinds of benefit data needed to facilitate EPA decision-making. Development of better information on pesticide use patterns—beyond the major crops—also would be helpful. Such improvements in the quality and quantity of pesticide use information would bolster public confidence and allow risk-benefit decisions to be made more easily.

Integrated Pest Management

ACPA and our industry continue our strong support of measures to sustain and bolster Integrated Pest Management. However, IPM does not and cannot mean abandoning chemical pesticides. The success of IPM depends on the continued availability and safe, responsible use of a variety of effective pest controls.

Our member companies have developed methods and recommendations for use of their products in concert with cultural and biological pest control. New products have come on the market, and many more are in the research pipeline, which will further enhance farmers' IPM performance.

According to *Crop Production and Crop Protection,* a comprehensive 1994 study of estimated global losses in major food and cash crops by leading agricultural researchers at the Universities of Bonn, Hanover and Christian-Albrechts, in Germany, Integrated Pest Management "combines care and concern for natural resources and the environment with responsible and economic use of modern methods to produce safe and wholesome food." It accounts for all "known factors," including "location, crop rotation, tillage systems, soil fertility, irrigation practice, energy utilization, seed selection, plant nutrition, and crop protection (biological, physical and chemical)." The authors conclude that IPM "represents a logical way forward between the extremes of ultra intensive agrosystems and low output organic farming."

The United Nations, the World Bank and other world bodies project that by 2050 global agriculture must be able to provide for as many as 11 billion people, *with less cropland and each person demanding better, more nutritious diets than those available today.* Experts agree that without continued investment in modern crop protection technologies (in both enhancements to existing products and in new product research), yields of the world's major food crops—rice, wheat, corn and soybeans—would fall dramatically. So-called "minor crops" could suffer an even larger production setback.

Harmonization—Global and Domestic

We endorse the efforts of H.R. 1627 to address the important role which international harmonization of tolerances can play in increased regulatory efficiency and confidence, world wide. This provision of H.R. 1627 would also serve to enhance world trade of U.S. farm production.

Tolerances established by the Codex Alimentarius Commission are subject to standards which are, generally, as strict—and in some cases more strict—than those of the United States. Where possible, EPA should harmonize our tolerances with those set by the Commission. Where departures are appropriate (either higher or lower), EPA should be able to support such departure with reliable scientific data and rationale.

Similarly, the promotion within the United States of national uniformity for tolerances will lead to increased public protection, and confidence in the safety of the food supply. ACPA supports the concept of national uniform tolerances for pesticide products to assure that fresh produce and processed foods are treated under the same pesticide residue limits in every state, enhancing public confidence and interstate commerce. With limited exceptions, based on good science, states should be precluded from setting tolerances which differ from those established nationally.

Conclusion

Let me reiterate. Food safety reform is needed now. The 37-year-old Delaney Clause is a four-decade throwback to the days when science could measure, generally, only in parts per thousand. Today, science measures in parts per million, billion and trillion. More importantly, scientific knowledge about human health has

advanced even further. The Delaney Clause imparts a choke hold on progress and safety in the supply to consumers of our nation's food.

Data on children's diets must be updated, and additional information obtained on dietary exposures to further ensure protection.

Benefits consideration is essential to a sound regulatory process governing crop protection.

Uniform regulatory processes—domestic and international—are essential key components of a modern approach.

At issue are both the science-based regulation of crop protection products currently approved for U.S. agriculture *and* the development of creative, newer, better products for tomorrow. With new product discovery-to-market time lines today taking up to 10 years or more, the year 2050 is but a hop, skip and jump away. H.R. 1627 will set the framework for industry and all of agriculture to continue to invest to meet that enormous challenge.

The world—a hungry world—is watching, and applauding, your leadership, Mr. Chairman.

Thank you.

Mr. BILIRAKIS. That is quite a responsibility.

Mr. Feldman—and with all due respect I ask this; please accept it the way I mean it—is your organization opposed to the use of all pesticides?

Mr. FELDMAN. No.

Mr. BILIRAKIS. No.

Mr. FELDMAN. I can embellish on that if you would like. I stated our goal for you so that you know we are not trying to blindside the committee or suggest that you know we are not above board in our goal and mission. We believe it is our duty as an organization, and we believe, in the public interest, this Congress and the Government should seek to make available to people the safest possible technologies to assist in a productive and profitable food production system, and the question is, how do you define safety, really is what it comes down to.

We have in our membership people ranging from sustainable ag to integrated pest management, organic farmers, who believe that cancer-causing pesticides are not necessary—no processors, I should add—who believe that cancer-causing pesticides are not necessary to a profitable and productive food supply. In fact, some of the staff up there can verify that we bring some of these farmers to the Congress once a year and have met with Mr. Roberts to share with them the fact that there are profitable farmers growing row crops, cotton, a whole range of commodities without a dependence on pesticides, and some of the commodities you heard that were dependent from previous witnesses on cancer-causing pesticides, wheat in Kansas, there are alternatives in those very communities, in those very States, that are not reliant on those materials.

That is what we are after, Mr. Chairman. We believe that there are some honest fears out there on the part of the agricultural community that the lack of access to these chemicals will hurt them economically, and therefore there needs to be assistance to those farmers. But we also believe that this committee is hearing from a lot of vested interests that have, with all due respect, Jay—that have a vested interest in selling chemicals, and that is not necessarily the farmers' interest, and that is what we are trying to get organizationally.

We are not out to take cancer-causing chemicals off the market tomorrow. We simply want to get to a point where farmers are using the safest possible tools.

Mr. BILIRAKIS. Mr. Feldman, I was trying to figure out if there was anything at all about the bill that you might like, and there is one area when you talked about the pesticide tolerances for safeguarding infants and children. You basically accented more resources, the need for more resources. So are you satisfied that the provisions of the legislation are basically adequate for that purpose but that more resources are needed, more money, more personnel? Is that what you are saying?

Mr. FELDMAN. Well, again, as I read the language in the bill, it seems that this is an exposure provision in terms of generating health and safety data to make a determination on childhood exposure.

I think Mr. Olson's testimony indicated and conforms to the NAS findings that there are a number of other issues that really need to be addressed such as developing organ systems, impact on developing organ systems being a big one, multiple exposure to chemicals, carcinogenic chemicals in particular, so that I think you are right in the sense that, give EPA the discretionary authority to do something and let them go ahead and do that. But given the reality of limited resources and a whole bunch of competing priorities, unless EPA is instructed to have very specific standards and guidelines for attacking this problem, a simple direction in this legislation to collect exposure data will not ensure that children are ultimately protected.

So it is a step, it is an important step, and I don't want to negate that as an important step, what this bill does, but I think we need to go beyond that if we are to achieve the goals that I hear members on this committee want to achieve.

Mr. BILIRAKIS. Thank you.

Ms. Brickey, you mentioned the new processes out there, new equipment, new chemicals, that are available to the farming industry, but that they are holding on to the old and not allowing them to be even considered. What do you suggest there? What do you have in mind?

Ms. BRICKEY. Well, all I can really suggest is what I have heard over and over from farmers who tell me that they want to change their practices and they are not sure how to do it, or there is too much risk involved, or they don't know how they are going to explain changing their practices to the bank when they go in for a crop loan.

But farmers who have changed their practices also say over and over that in many cases they had to play detective and learn what was out there themselves. Or an even better way has been hiring private crop consultants who come in and help farmers figure out how to change their practices, make it their business to know what are the three different ways you might accomplish the goal of growing this crop, and they have been able to use those techniques pretty successfully, but it is not widespread enough. There are not enough farmers doing it, and I don't believe there is enough encouragement coming from the Department of Agriculture or enough

leadership coming from the Department of Agriculture to make that happen.

Mr. BILIRAKIS. Okay. That is what I wanted to hear from you. Thank you very much. My time has expired.

Mr. Burr.

Mr. BURR. Thank you, Mr. Chairman.

Ms. Brickey, let me follow up on the question from the chairman. What would you suggest to encourage new pesticides on the market? I think you said that we need to get rid of the old and bring in the new. What specifically would you suggest that we do? Would you suggest that we streamline the approval process?

Ms. BRICKEY. I think there have already been some efforts made to streamline the approval process particularly for biocontrols and some of the new alternatives that are out there. I think, again, how quickly EPA can act on new technologies depends on their resources. They have had to shift resources from one area to another depending on what the Congress and the public emphasizes at a particular point in time as important. I think that if they had more resources I'm sure that they would try to look at more new alternatives more quickly.

But I also want to emphasize that the Department of Agriculture needs to play more of a role in helping farmers learn about nonchemical alternatives, new cultivation techniques, and other ways to grow crop that may not involve these chemicals we are talking about on the Delaney list. I think that is the way we need to go. I think that is the way fruit and vegetable growers need to go.

Mr. BURR. I don't know that the North Carolina apple growers would buy that though after the experience they just went through, and it is my understanding that the only thing that can solve the fungus problem is a chemical. So, you know, I'm not sure——

Ms. BRICKEY. Well, it depends in certain situations on whether there are truly no alternatives available, and I will concede to you that at some point in time there will be circumstances where someone will have to say we don't have an alternative available right now. But I really believe that once we can identify those situations. If you are talking about phasing a chemical out of use over maybe a 5-year period, there is time to develop these technologies.

Mr. BURR. Given that you would suggest that we go through this process of looking at every alternative, is it wrong to think that we ought to look and use the best science and the best analysis on the pesticide side, which I think some of you on this panel suggest that we shouldn't be spending the time on that?

Ms. BRICKEY. I think we should be spending a lot of time in looking at these chemicals, on what the health risks are and how serious they are. I think beyond that we have got to look very candidly at what kind of alternative technologies are out there and available. This is not something, frankly, EPA has been able to do very effectively by itself, and the history of this issue at the Department of Agriculture is not very bright either.

Mr. BURR. Let me ask Mr. Vroom to comment on any of that he would.

Mr. VROOM. On the question of regulating the risk?

Mr. BURR. Correct.

Mr. VROOM. I think the agency has done an adequate job over time. Certainly there are wrinkles and points in time where, you know, individual products get caught in that purgatory of science not being able to make a clear decision, and, again, you come back to regulators being risk averse, preferring to put off until tomorrow a decision that otherwise they could make today with existing information. I think we find for pesticide registrants a continuing cycling of the agency asking for one more study before they will decide on a use decision or a full registration of a product.

I think the system works pretty well. It can always work better, and there can be more room for greater market incentives to come into play without having to put an absolute drop dead kind of a mechanism in place that runs older products off the market prematurely.

I think the marketplace can be allowed to work very effectively. Again, the marketplace is today, through farm customers that we respond to, sending signals for more environmentally safe products, products that biodegrade more rapidly, that have less chance for drift, and, overall, protect workers and human health in general better. So the marketplace does send those signals.

Mr. BURR. Would your membership agree with Ms. Brickey that we have tried to streamline the approval process?

Mr. VROOM. There have been initial steps made and some benefits realized already in terms of fast track approval for lower toxicity products. Is it working in a way that has had a significant national impact so far? No. Again, because the agency does not have those resources, and I would again point out that the agency has spent an incredible amount of resources defending itself from litigation in the last few years, and those resources could have been spent doing other things proactively.

Mr. BURR. Certainly we find that to be true in other agencies.

Mr. Feldman, just a follow-up to the comment. You made a statement that we should be concerned with farmers and the process, and I'm curious, just from your association, should the consumer be thought of in this process? Should we be considering the consumer?

Mr. FELDMAN. Sure, definitely. Obviously the question is whether the committee needs to establish a health-based standard that in the process protects consumers as well as farmers.

Mr. BURR. Do you personally—in your association, do you have trust that the EPA can confidently go out and protect the health of the citizens of this country?

Mr. FELDMAN. The current system right now is not protecting the health of consumers nor the health of farmers. In fact, a farmer——

Mr. BURR. I'm talking about the agency.

Mr. FELDMAN. Right. So the agency with responsibility for implementing and enforcing existing law does not, in my view, provide adequate protection currently. I think to answer you question——

Mr. BURR. Do you have any scientific studies from our organization that would prove that the EPA has——

Mr. FELDMAN. Well, in my testimony I cite internal reviews by the inspector general, for instance, on the laboratory audit program which shows that EPA is ill equipped to ensure the credibility of the data that it receives, the underlying health and safety studies

which are laboratory animal studies. I'm not doing that primary research obviously, but this is an inspector general report, and the same is true for inert ingredients which are a major part, as you know, of pesticide product formulations that the inspector general says are not adequately tested to protect the health and safety of both farmers and consumers, anyone that comes into exposure with the material.

What I was going to say relating this to farmers is, there is one farmer that comes to mind in North Carolina, a nursery grower who used a pesticide, benlate, which was mentioned earlier today, as one of those affected by Delaney, and lost his nursery. He attributes the loss of his nursery—this is a North Carolina farmer—to the use of this product and in trying to get information on what EPA knows about contamination about that product, cross-contamination with other materials at the point of manufacture, what EPA is doing to evaluate levels, breakdown products. There are unregistered products that have been found in this, an unregistered product called fusilizol which is found in benlate, a cross-contamination possibly with sulfunurea, which is a very potent herbicide. This is a farmer who is frustrated because he trusted the registration process and he has lost his nursery. So that is what we would like to prevent through this sort of discussion so that everyone is protected.

Mr. BURR. I would certainly suggest that I would like to see that farmer protected.

Mr. FELDMAN. I would be to happy to talk to you.

Mr. BURR. As well as those who are out of business because they have lost their crops in North Carolina and in Virginia, in the bordering States, where this fungus exists, and that we elected officials owe it to the constituents to present something to them to solve the problem that protects the health of individuals and works on good science and not on emotions.

I thank the panel.

Mr. BILIRAKIS. I thank the gentleman.

Dr. Coburn.

Mr. COBURN. Thank you.

Mr. Olson, let me just follow with you a minute. I have read the NAS recommendations, and we have had testimony by three separate people that would disagree with your interpretation of what this bill does with respect to the NAS, and I don't have a large contention with what the NAS says. Is it your position that this needs to be absolutely spelled out in the bill rather than to give the EPA—I'm not talking about funding—but rather than to give the EPA the flexibility to do that, yes or no?

Mr. OLSON. It is our position that the bill should spell out that the Academy recommendations must be followed, but simply saying that and not changing the FIFRA Codex override or the benefits override doesn't do anything.

Mr. COBURN. Okay, but that is not a yes or no answer, right? Okay.

Mr. Feldman, you alluded a minute ago to pesticide data on drift and farm workers. Would you mind forwarding that to my office?

Mr. FELDMAN. I would be happy to.

Mr. COBURN. I would like to see that and the study done to that. And I want to follow up on one question that our chairman asked you. Can you name a pesticide presently that is sold that you or your organization would consider safe?

Mr. FELDMAN. Pesticides that we consider——

Mr. COBURN. Safe?

Mr. FELDMAN. Acceptable under——

Mr. COBURN. No, I said safe.

Mr. FELDMAN. Biological pesticides for which we know the inert ingredients we consider safe.

Mr. COBURN. I'm talking organic pesticides.

Mr. FELDMAN. Well, these are registered as pesticides.

Mr. COBURN. Okay, I'm talking organic pesticides, I'm not talking biologic pesticides. Is there an organic pesticide which your organization would consider safe? Is there any?

Mr. FELDMAN. I guess I can't answer that question. Let me try to answer that question in context. There are pesticides which we consider acceptable in various pest management scenarios.

Mr. COBURN. That are organic?

Mr. FELDMAN. That are organic pesticides.

Mr. COBURN. Fine.

Then I want to follow with one last question, and I'm not harping because basically I'm really interested in health and safety as a physician. I'm worried about this concept of safest at any cost, and I think that was—you know, I want to have an understanding of where you are on that. Is there one small amount of cost that is acceptable, one small amount of risk anywhere that is acceptable for a pesticide? Can benefits ever be used to consider coming off absolute safety to allow some area of less than absolute safety? Is there a position that your organization would find itself in to where that would be acceptable?

Mr. FELDMAN. I think that is excellent question, and I think the short answer to that is yes. The long-term answer to that is in the context of a clear evaluation of the range of alternatives, and that is what is missing in this process.

If we adopt this legislation we are setting in stone a standard that we believe allows too much risk without an adequate evaluation of whether that is necessary risk.

Mr. COBURN. Okay, but the real crux I want to get to is too much risk. Where is the scientific data that says that is too much risk? That is my real question. I want the risk to be low, but I want to see the data that says it is too much.

Mr. FELDMAN. Excellent question. You heard toxicologists today talk about risk assessment, and the word they all used was "uncertainty."

Mr. COBURN. No, they all used "negligible risk," the two that testified here.

Mr. FELDMAN. They also used the word "uncertainty."

Mr. COBURN. But they both recognized and said they would be happy with the word "negligible risk."

Mr. FELDMAN. I understand that, but then when pressed and asked about risk assessment modeling, everybody that testified used the word "uncertainty." The question is where you want to put the burden. Do you want to put the burden on the individual

who is exposed or the farmer and say you must assume the uncertainty associated with the inert ingredients, with the fact that we don't have multiple modeling for multiple exposures, with the fact that we don't have modeling for sensitive population groups, with the fact that we don't have food residue and nondietary exposure cumulative effects?

Mr. COBURN. Let's assume that we are going to take NAS and include that. Now say that in the context of including the NAS recommendations within that. Say what you just said again, because in fact we will consider those things if in fact we follow the NAS recommendations, correct?

Mr. FELDMAN. If in fact you follow the recommendations, correct, except for synergistic effects and except for inert ingredients, which are two major exceptions here. The reality is, if cost is an issue the cost problem is on proving the safety side. That is the problem. If cost is really an issue for this committee, which I believe it is, then the question is, how do we come up with all the money necessary to assure the consumers, your constituents, that their children are not going to be in that risk factor, that their children are not going to get the brain cancers or the soft tissue sarcomas or the leukemias? What you are telling your consumers is, you are going to have to live with this level of uncertainty because we believe it is necessary to food production, and that is where we have not proved the necessity.

Mr. COBURN. That is right. That is where the discussion is in terms of whether there should be or should not be a tradeoff in that area.

Mr. FELDMAN. There is always a tradeoff. The question is, are we getting to a national goal with a health-based standard that allows us to ensure the people we work with that we have done the best possible job we can to get the farmer the tools he needs to prevent risk and to prevent adverse effect.

Mr. COBURN. And that goes to the point, safest at what cost, and that is the real issue, safest at what cost.

Mr. FELDMAN. Can I add one more thing you might want to consider on this?

Mr. COBURN. Well, I would like you to do that, but I'm out of time so I would have to defer to the chairman.

Mr. BILIRAKIS. Without objection, you may, but keep it short.

Mr. FELDMAN. Yes. Cost is a very big issue, and most of the cost we focus on is the cost at the grocery store to the consumer, and that is an important cost. But there is also a larger cost that the Congress, especially this Congress, has focused on, and that is the cost to the taxpayer, and the reality is, what really needs to be done, for the farmers, for the consumers, and overall is to look at the cost to the taxpayer of using pesticides versus the cost of the alternatives, and that is where you will find with ground water contamination, drift—you know, there is a lot of property damage to farmers who are suing all the time because of pesticide damage. There is a study which we cite in the testimony. It talks about $8 billion in costs a year, done out of Cornell University. That is what this Congress has an opportunity to look at: How do we relieve the taxpayer of the costs of production methods that are un-

necessarily dependent on toxic inputs? And I think there are great opportunities there, and I appreciate your questions.

Mr. COBURN. Thank you.

Mr. Chairman, I just wanted to add one thing for the record. Earlier today it was cited that benzene and formaldehyde were considered inert ingredients. I don't know an organic chemist anywhere that would consider benzene or formaldehyde inert.

Mr. OLSON. That is exactly right, and that is why we are concerned that EPA's current policy in the current law would consider those inert ingredients.

Mr. COBURN. But I wanted to make that clear for the record.

Mr. BILIRAKIS. I thank the doctor.

Dr. Ganske.

Mr. GANSKE. Thank you, Mr. Chairman, but I'm going to forego any questions since I had to be absent for a period of time.

Mr. BILIRAKIS. That being the case then, I declare this hearing at an end, and, again, I appreciate very much the last panel particularly being as patient as you have been. I appreciate your help. Thank you.

[Whereupon, at 1:45 p.m., the subcommittee was adjourned.]

[The following statements were submitted for the record:]

PREPARED STATEMENT OF WARREN E. STICKLE, PRESIDENT, CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION

INTRODUCTION

I am Warren E. Stickle, President of the Chemical Producers and Distributors Association (CPDA) and I would like to submit the following statement for the record regarding the food safety provisions contained in Title IV of H.R. 1627, the "Food Quality Protection Act of 1995."

By way of introduction, CPDA is a voluntary, non-profit 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.

We at CPDA would like to commend Chairman Bilirakis and members of the Subcommittee on Health and Environment of the House Commerce Committee for holding hearings on the food safety provisions of this bill. We at CPDA believe it is time to move forward in revising the outdated Delaney Clause so that pesticide residues are regulated in keeping with modern science and technology. We believe that H.R. 1627 offers a fair and reasonable approach to the regulation of pesticide residues on foods—an approach that is based on sound science rather than public misperception fueled by emotion. H.R. 1627 recognizes the important benefits of pesticide use in terms of ensuring a wholesome, healthy, nutritious and affordable food supply.

On May 23, 1995, the House Subcommittee on Department Operations, Nutrition & Foreign Agriculture, chaired by Representative Bill Emerson (R-MO), reported out the food safety provisions of H.R. 1627. We at CPDA urge members of this Subcommittee to join with their colleagues on Chairman Emerson's panel in adopting this important legislation.

My comments today will include a discussion of CPDA's strong support for the amendments to the Federal Food, Drug and Cosmetic Act (FFDCA) contained in Title IV of H.R. 1627 which allow the EPA Administrator the discretionary authority to determine what is a negligible risk in setting tolerances for pesticide residues in foods and direct the Agency to take into consideration the important benefits of pesticide use. The flexibility built into these amendments will ensure that EPA does not become bound by rigid, numerical limits which would preclude the consideration of the countervailing benefits of pesticide usage and prohibit the Agency from regulating pesticides according to the best available science. We at CPDA believe that the food safety provisions of H.R. 1627 will permit the EPA Administrator to prioritize more serious risks and thus allow for the more efficient utilization of scarce Agency resources. My other comments today will convey CPDA's support for

related food safety issues which include the national uniformity of tolerances, the international harmonization of pesticide standards, import tolerances, and inerts.

THE NEED TO REFORM THE DELANEY CLAUSE: IMPACT OF LES VS. REILLY

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 a number of different pesticides 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.

EPA Administrator Carol Browner has stated that the Agency is implementing the court decision although the Agency continues to believe the pesticides involved "pose only a negligible risk to public health" and that a negligible risk standard "reflect[s] sound public policy and science while at the same time assuring the overall safety of the food supply."

The "zero risk" standard is simply unworkable for establishing reasonable risk evaluation. When Delaney was enacted in the late 1950's, 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. Under a strict zero risk standard, if any testing results show minute levels of carcinogens, regardless of how negligible the associated risk of dietary exposure, EPA will not register or grant a food use tolerance for the pesticide. We at CPDA believe that it is inappropriate to use 1950's science to regulate modern chemicals.

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.

Moreover, according to the National Cancer Institute, there is no scientific evidence that ingestion of pesticide residues on fruits and vegetables causes cancer in human beings. Medical experts agree, the benefits of eating fruits and vegetables far outweigh any potential risks.

To illustrate the low levels of risk associated with dietary exposure to pesticides, a 40-pound child could eat 340 oranges every day for the rest of his or her life and still not consume the amount of pesticide residues found to cause health problems in laboratory mice. By the same token, a 150-pound adult could eat 875 pounds of broccoli, and a 20-pound child could eat 873 apples.

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.

In the absence of legislative intervention, EPA is bound to implement the strict interpretation of the court decision in *Les* v. *Reilly*. We at CPDA believe it is important to move forward with a legislative fix to Delaney as quickly as possible to avoid the cancellation of numerous pesticides that help keep our food supply the safest and most abundant in the world. We believe that the negligible risk provisions set forth in H.R. 1627 offer a good remedy to the present Delaney dilemma.

TOLERANCE STANDARDS

We at CPDA strongly support the food safety provisions contained in Title IV of H.R 1627. The bill would create a single negligible risk standard for tolerances for pesticide residues in raw commodities and processed food. In so doing, H.R. 1627 would permit the presence of a pesticide residue in a processed food made from a raw agricultural commodity as long as the concentration of the pesticide residue in the processed food when ready for consumption or use is within the tolerance limits established for the raw food. This provision of H.R. 1627 allows all foods containing pesticide residues that are within a tolerance to be considered safe, and not adulterated. CPDA believes that this provision is important in that it sets forth one, uniform consistent standard for both raw and processed foods.

We at CPDA strongly support the creation of a single negligible risk standard for pesticide residues in establishing tolerances for processed foods and raw agricultural commodities. Under current Section 408 of the FFDCA, EPA sets tolerances for pesticide residues remaining in raw agricultural commodities. Under Section 409 of FFDCA, EPA sets food additive tolerances for pesticide residues that concentrate in processed foods above raw food tolerances, or are the result of pesticide application during or after food processing.

In establishing pesticide tolerances, EPA utilizes a conservative set of assumptions regarding dietary exposure to pesticides. These include assumptions that: 1) the pesticide is applied at the highest application rate allowed by the product label; 2) the crop is treated the maximum number of times; and, 3) only the minimum permissible interval is allowed between applications.

However, experience shows that the level of pesticide residues found in foods declines significantly from the farm to our dinner tables. In its article entitled, "The Life Story of a Tomato," which appeared in the May/June 1990 issue of *EPA Journal*, the authors write:

> "[T]olerances are intended to apply to treated agricultural commodities when they first enter into commerce, starting at the 'farm gate'... By definition, tolerances represent residue levels that are protective of public health. As our tomato story suggests, however, pesticide residues are generally reduced at each step between the farm gate and the dinner table so that they are often well below tolerance before the commodity reaches the consumer. And in a majority of cases, washing, peeling, and home cooking of foodstuffs also serve to reduce any remaining residues in consumer foods... As a practical matter, tolerances thus represent 'upper limits' of pesticide residues that rarely occur in ready-to-eat food commodities."

We at CPDA agree with the authors of this EPA article.

Currently, under EPA's "coordination policy," if a processed food tolerance is needed but is prohibited under the Delaney Clause, the corresponding raw food tolerance is not permitted. In *California* vs. *Browner*, a lawsuit concerning pesticides and the Delaney Clause, the parties sought a court order requiring EPA to revoke a number of raw food tolerances (Section 408) associated with processed food tolerances (Section 409) which are barred by the Delaney Clause. On February 8, 1995, the U.S. District Court for the Eastern District of California approved a settlement agreement in *California* v. *Browner*. Under the consent decree, EPA will be required to set policy, in accordance with specific timelines mandated by the court, that could lead to the cancellation of a significant number of uses of approximately 37 pesticides and further review of more than 40 others. In all, about 80 raw food tolerances that are associated with existing or needed processed food tolerances could be revoked. Moreover, under the consent decree, EPA must decide whether any of approximately 60 processed food tolerances are subject to revocation under Delaney.

The impact of the *California* vs. *Browner* consent decree, in combination with the July 1992 *Les* vs. *Reilly* Ninth Circuit Appeals Court ruling, will be a significant disruption of this nation's food supply and a drastic reduction in the arsenal of pest control tools available to U.S. farmers. Less choices mean higher prices for both the American consumer and the American producer of food.

We at CPDA believe that the fair and reasonably constructed food safety provisions of H.R. 1627 will help us avert the potential food safety crisis and market disruption that will surely ensue if we do nothing.

NEGLIGIBLE RISK AND CONSIDERATION OF BENEFITS

Under H.R. 1627, 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. This provision, supported by CPDA, requires the development and implementation of procedures to ensure that pesticide

tolerances adequately safeguard the health and safety of infants and children. As such, it responds to the recommendations made by the National Academy of Sciences in its report "Pesticides in the Diets of Infants and Children."

In other provisions of H.R. 1627 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. In particular, the EPA Administrator would be required to take into account aggregate pesticide use and residue data collected by the U.S. Department of Agriculture. We at CPDA are particularly supportive of the requirement in H.R. 1627 that EPA 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.

We at CPDA support the discretionary flexibility which H.R. 1627 provides the EPA Administrator in determining what is a negligible risk. We do not believe that the EPA should be bound by a numerical straitjacket in defining a negligible level of risk. Moreover, we support those provisions in H.R. 1627 which direct the EPA Administrator to take into consideration the countervailing benefits of pesticide use.

In so doing, H.R. 1627 permits the EPA Administrator to avoid more hazardous risks that might otherwise occur in the absence of an established tolerance for a particular pesticide chemical residue, even if that tolerance poses a greater than negligible risk. For example, under H.R. 1627, the EPA Administrator could approve a level of a pesticide chemical residue in or on a food that poses a greater than negligible dietary risk to consumers of the food if: 1) use of the pesticide protects humans or the environment from adverse effects on public health or welfare that would, directly or indirectly, result in greater risk to the public or the environment than the dietary risk from the pesticide chemical residue; 2) use of the pesticide avoids risks to workers, the public, or the environment that would be expected to result from the use of another pesticide or pest control method on the same food that are considered to be greater than the risks that result from dietary exposure to the pesticide chemical residue; or, 3) the availability of the pesticide would enable domestic growers to maintain the availability of an adequate, wholesome, and economical food supply for consumers, taking into account national and regional effects.

We at CPDA do not believe that a health based tolerance standard which ignores a benefits evaluation, such as that proposed by the Administration in legislation (H.R. 4362) introduced during the 103rd Congress, 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 in the absence of any consideration of benefits would likely cause the revocation of tolerances which do not pose a real health threat to the American public and would likely cause a disruption of the nation's food supply.

"PIPELINE PROVISIONS"

CPDA supports the so-called "pipe-line" provisions in H.R. 1627, as reported out of the House Subcommittee on Department Operations, Nutrition & Foreign Agriculture, which provide that where a tolerance or exemption for a pesticide residue was revoked, suspended, or modified, a food that was legally treated with the pesticide would not be considered unsafe provided that the residue does not exceed the previously authorized tolerance level. EPA would have the authority to declare such food unlawful and issue a determination that consumption of the legally treated food during the period of its likely availability in commerce would pose an unreasonable risk.

This provision allows the use of existing food stocks that were treated with a lawful pesticide and protects against unnecessary destruction of legally treated food. In addition, this provision would ensure that food producers are not unfairly penalized for use of legal pesticides that were subject to regulatory action at a subsequent date. We at CPDA urge members of this Subcommittee to support this provision in H.R. 1627.

DATA COLLECTION ACTIVITIES

As mentioned previously, CPDA supports those provisions in H.R. 1627 which require the 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. To this end, CPDA supports those provisions of H.R. 1627 which require the Secretary of Agriculture, in consultation with the EPA Administrator and the Secretary of Health and Human Services, to coordinate the development and imple-

mentation of survey procedures to ensure that adequate data on food consumption patterns of infants and children are collected.

We at CPDA believe that the collection of this data will be a positive step forward in implementing the recommendations contained in the National Academy of Sciences report, "Pesticides in the Diets of Infants and Children," which call upon EPA to consider the unique aspects of children's diets and non-dietary sources of pesticide exposure.

In addition, CPDA is supportive of the directive contained in H.R. 1627 which directs the Secretary of Agriculture to collect data of statewide or regional significance on the use of pesticides to control pests and diseases of major crops and crops of dietary significance, including fruits and vegetables.

The collection of adequate pesticide usage data is the key to arriving at a realistic estimate of dietary exposure to pesticides. In the absence of such data, some would advocate an approach which utilizes a "worse case" scenario under which assumptions of maximum dietary exposures are made. We at CPDA do not believe that such an approach avails itself to sensible regulation of pesticides.

INERTS

We at CPDA commend the authors of H.R. 1627 for their exclusion of "inerts" from the definition of a pesticide chemical. The comprehensive food safety bill introduced by Representatives Lehman, Bliley and Rowland during the 103rd Congress would have included inerts in the definition of a pesticide chemical. In addition, this definition was also found in the Administration's package of FIFRA reform amendments (H.R. 4329). We at CPDA have long been opposed to any efforts which would expand the definition of a pesticide to include inerts.

If the definition of a pesticide chemical were to be expanded to include inert ingredients, residue testing would have to 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 metabolites (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 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.

I would like to reiterate CPDA's support of the decision made by the principle authors of H.R. 1627 to exclude inerts from the definition of a pesticide chemical.

NATIONAL UNIFORMITY OF TOLERANCES

We at CPDA strongly support those provisions in H.R. 1627 which establish a national uniform system of tolerances. These provisions state, "[N]o 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 residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination."

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 eighteenth century, we need to plan for the twenty-first century by adopting the national uniformity provisions in H.R. 1627.

INTERNATIONAL HARMONIZATION OF STANDARDS

While CPDA supports H.R. 1627 for its provisions on national uniformity of tolerances that would require all states and local governments to establish tolerances identical to those set by EPA at the federal level, we similarly endorse H.R. 1627 for its provisions which encourage the international harmonization of residue standards. Specifically, in establishing a tolerance for a pesticide chemical residue, EPA would be directed to determine whether a Maximum Residue Level (MRL) has been established by the Codex Alimentarius Commission (Codex). If a Codex MRL is established and EPA chooses not to accept it in setting a tolerance, the Agency Administrator would be required, as part of the final tolerance decision, to publish a determination with supporting data that the Codex level is not supported by adequate and reliable data or would not protect the health of U.S. consumers. EPA would also be required to show that the effect of the tolerance on the availability to consumers of an adequate, wholesome and economical food supply does not outweigh the risk posed by the pesticide residue.

I refer your attention to the Congressional Research Service (CRS) section-by-section analysis and summary of this bill as considered by the House Subcommittee on Department Operations, Nutrition and Foreign Agriculture as an amendment in the nature of a substitute to H.R. 1627 during that panel's May 23, 1995 markup. In its summary, CRS states, "This new subsection brings our tolerance setting system into compliance with the spirit of the Uruguay Round Agreement of the World Trade Organization (formerly known as the General Agreement on Tariffs and Trade) and other international trade agreements for it tries to avoid unjustified restraints on trade and to make U.S. regulatory decisions consistent with our international trade agreement."

We at CPDA support this provision on international harmonization. We believe that it will improve the competitive position of the United States in global agricultural trade markets by encouraging uniformity of pesticide standards across foreign boundaries. At the same time, we believe that this provision ensures appropriate safeguards of the safety of the U.S. food supply and provides the EPA Administrator the necessary flexibility to depart from those Codex limits which do not appropriately address domestic pesticide use and consumption patterns.

PROTECTION OF EXISTING IMPORT TOLERANCES ON CANCELLED/SUSPENDED REGISTRATIONS

While CPDA supports many of the provisions in H.R. 1627 as discussed above, we would like to see the inclusion of language which would ensure that some necessary import tolerances are not revoked. As currently drafted, H.R. 1627 could be interpreted to mandate the revocation or suspension of some import tolerances, if the EPA Administrator, acting under FIFRA, cancels the registration of a pesticide chemical that is labeled for use on a particular food. We at CPDA believe that this language would create a new paradox. It would prevent the establishment of tolerances for commodities which are legally treated by our trading partners, but for non-safety concerns would be blocked from U.S. trade, solely due to the fact that the Administrator does not have on file a valid and active registration. Under this language, the current practice of setting import tolerances would no longer be possible. The U.S. food producers and chemical manufacturers of crop protection chemicals need this non-safety issue clarified to permit trade with NAFTA and Gatt partners. CPDA believes that clarifying language should be included in H.R. 1627 which would give EPA the discretion to maintain tolerances, in certain circumstances, even when a pesticide is not registered for a particular use in the United States.

Such modifying language would allow the EPA Administrator to maintain an import tolerance and exempt it from mandatory suspension if : 1) EPA has made the basic toxicological safety findings necessary to maintain a tolerance for at least one food use of a particular pesticide in the United States; 2) U.S. tolerances exist for other uses, but no U.S. registration exists that would permit application of the pesticide to those raw agricultural products or processed foods; and, 3) the pesticide has been lawfully applied outside the United States to those products or foods, which in turn are imported into the United States.

Current controversy over EPA's proposal to revoke tolerances for some uses of the fungicide folpet provide an example of the need for modifying language. Until the late 1960's, folpet was registered for use on a number of U.S. crops, but the underlying registrations for all uses except avocados are now suspended. However, folpet continues to be used on grapes, cranberries and other crops outside the U.S. Any revocation of folpet tolerances for those crops could have a devastating impact on the wine and other industries. CPDA would like to recommend that an amendment

be included in H.R. 1627 which would ensure that such a scenario, as described above, does not occur.

Specifically, CPDA suggests that new language be added to Section 405 of H.R. 1627 which amends FFDCA Sections 408(j)(2) (revocation of tolerance or exemption following cancellation of associated registration) and 408 (j) (3) (A) (suspension of tolerance or exemption following suspension of associated registrations) to stipulate that revocation or suspension of a tolerance will not be pursued provided that the pesticide chemical is lawfully used outside the United States on another raw agricultural product or processed food that is imported into the United States.

CONCLUSION

We at CPDA look forward to working with the Subcommittee on Health and the Environment concerning amendments to the Federal Food, Drug & Cosmetic Act (FFDCA), and respectfully urge passage of Title IV of H.R. 1627.

PREPARED STATEMENT OF THE NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

The National Association of State Departments of Agriculture (NASDA) is the nonprofit association of public officials representing the Commissioners, Secretaries and Directors of Agriculture in the fifty 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. 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 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 takes an average of two years if all necessary data has 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 U.S. 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, NASDA believes that H.R. 1627, the Food Quality Protection Act of 1995, 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 U.S. to continue to produce the safest, most economical, and most abundant food supply in the world. NASDA strongly supports passage of H.R. 1627 and encourages the House Commerce Committee to move quickly to favorably report the bill. H.R. 1627 is the most balanced and responsible piece of legislation pending before Congress.

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 sensationalized emotional falsehoods perpetuated by unqualified "experts" who believe that pesticides should be eliminated across the board.

RIGID NEGLIGIBLE RISK STANDARD

The FFDCA should be amended to eliminate the outdated "zero risk" Delaney Clause, replacing it with a nationwide "negligible risk" standard for pesticide residues in all food. 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. H.R. 1627 allows EPA to employ its expert judgment unhindered by a numerical straitjacket.

LIMITATION OF BENEFITS

H.R. 1627 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.

CANCELLATION AND SUSPENSION

NASDA believes that statutory changes are necessary to permit EPA to remove hazardous pesticides from the market with reasonable speed. H.R. 1627 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 accelerate the suspension and cancellation procedures.

Amendment Needed to H.R. 1627—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.

TOLERANCE UNIFORMITY AND FEDERAL PREEMPTION

A tolerance uniformity provision is indispensable to preserve EPA's leadership in pesticide regulation and to avoid consumer confusion and unreasonable burdens on interstate commerce caused by special state tolerance requirements. NASDA strongly supports the uniformity provisions of H.R. 1627.

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. During consideration of H.R. 1627, the House Ag-

riculture Subcommittee on Department Operations, Nutrition, and Foreign Agriculture included provisions to provide sensible, uniform federal/state regulation of pesticides through language calling for federal/state preemption of local regulations while allowing local input into the federal/state regulatory process. NASDA strongly supports these provisions.

REREGISTRATION

Amendments to FIFRA are needed to ensure that pesticide registrations and supporting data are current. Pesticide registrants should periodically submit scientific data and other information sufficient for EPA to determine whether existing registrations are proper. This reregistration process should identify benchmarks for data submission and EPA review.

MINOR USE

NASDA strongly supports the minor use provisions contained in H.R. 1627 and H.R. 1352, a bill introduced by Representative E (Kika) de la Garza and House Agriculture Committee Chairman Pat Roberts.

The provisions in these bills 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.

If the comprehensive bill, H.R. 1627, cannot be passed by the 104th Congress, it is extremely important to pass H.R. 1352 as a stand alone bill.

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, 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.

FEDERAL AGENCY COORDINATION

Consultation and coordination within the federal government on food and pesticide regulations need improvement. Currently, consultation among EPA, U.S. Department of Agriculture (USDA), and FDA primarily occurs in the form of written comments during cancellation of a pesticide's registration. Given the linkage among pesticide uses, agricultural production and food safety, the three regulatory agencies involved must consult more effectively and regularly. Moreover, communication and coordination among the three federal regulatory agencies and the state regulatory agencies needs improvement.

SECTION 18S

In order to facilitate timely and equitable approval of section 18 emergency exemptions, NASDA recommends a consistent system for issuing section 18s before section 3 registration is complete. States requesting a section 18 for using the same product on the same commodity are currently dealt with individually resulting in the product being available in some states and not in others where the same pest problem exists.

NASDA also believes EPA's requirement for aquatic residue and avian incident monitoring for section 18 approvals should be rescinded. This burdensome requirement seems to contradict an October 29, 1992 decision on registration and reregistration requirements made by EPA based on the recommendation of the Ecological, Fate and Effects Task Force. In the October 29 memorandum, then-administrator Linda Fisher stated: "More specifically, OPP will no longer require avian and aquatic field testing, except in unusual circumstances. Rather decisions will be based on lab testing, incident data and other information which can easily be collected to enable the program to better characterize potential risk." While the above policy was specifically designed for registration and reregistration, it appears to be inconsistent and unnecessary to require such field data on a section 18 exemption when no such requirement is placed on the registration of the product.

Amendment Needed to H.R. 1627—Language should be included in H.R. 1627 which requires EPA to make the section 18 system consistent. A further provision is needed to rescind the aquatic residue and avian incident monitoring for section 18 approvals. An amendment should also ensure that crop grouping is recognized and EPA handle crops in the same family equally when approving a section 18.

CERTIFICATION & TRAINING

NASDA supports a change to the federal/state match requirements for the Certification and Training funds from EPA, making the requirements consistent with other FIFRA requirements. The current match for certification and training funds is 50/50 and the other FIFRA match requirements are 85/15. NASDA recommends that the certification and training match be 85/15 and phased-in over a three year period. Such a change would not increase the budget requirements or exposure to the federal government. It would simply reduce the funding mandate on states.

Amendment Needed to H.R. 1627—A provision should be included in H.R. 1627 which modifies the certification and training matching fund requirement. The provision should change the match to 60/40 the first year, 70/30 the second year, and 85/15 the third and future years.

CONCLUSION

Allow NASDA to concluded by once again stressing the importance of passing legislation to reform pesticide regulations in the 104th Congress. NASDA believes it is essential. In fact, NASDA believes that pesticide regulation reform should be contained in the 1995 Farm Bill. Even though FIFRA is normally not debated as part of the Farm Bill, the only way to assure passage of pesticide regulation reform is for the House Agriculture Committee to include it in their version of the 1995 Farm Bill. Mr. Chairman, it is imperative that this Congress reform pesticide regulations.

Thank you for your consideration of NASDA's views as state regulators on this important issue.

FOOD QUALITY PROTECTION ACT OF 1995

THURSDAY, JUNE 29, 1995

HOUSE OF REPRESENTATIVES,
COMMITTEE ON COMMERCE,
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:54 p.m., in room 2322 Rayburn House Office Building, Hon. Michael Bilirakis (chairman), presiding.

Members present: Representatives Bilirakis, Burr, Bilbray, Whitfield, Ganske, Norwood, Coburn, Waxman, Brown, Stupak, and Pallone.

Staff present: Mary M. McGrane, majority counsel; Howard Cohen, majority counsel; Melody Harned, majority counsel; Eric Berger, professional staff member, and Kay Holcombe, minority professional staff member.

Mr. BILIRAKIS. The hearing will come to order.

The United States enjoys the world's safest, most abundant and affordable food supply. Maintaining the wholesomeness, the variety and the low cost of our Nation's foods is critical.

For a number of years, scientists and the Environmental Protection Agency and those involved with growing and processing our Nation's food supply have agreed that the Delaney Clause is obsolete. It was based on the scientific knowledge and techniques of the 1950's. The Delaney Clause greatly exaggerates the degree of risk and ignores any benefits to society from the use of safe crop protection tools. Congress and this administration need new legislation that will give EPA the flexibility that it needs to regulate pesticide use, as well as ensuring that strong standards will remain in place, particularly standards for the health of infants and children.

The Bliley-Towns Bill, H.R. 1627, replaces the Delaney Clause with a negligible risk standard which moves EPA away from the rigid zero risk standard. It also contains a number of provisions that would ensure sufficient consideration for the safety of infants and children. These would fulfill many of the recommendations of the National Academy of Science's report, without unduly restricting EPA's scientific judgment. Some of the provisions of H.R. 1627 that implement the NAS recommendations include collection of data on food consumption patterns of infants and children, improved surveillance of pesticide residues, increased sampling of foods most likely consumed by children and toxicity testing procedures and methods of risk assessment that take into account the unique characteristics of infants and children.

These provisions would build upon the current EPA methods of protecting infants and children which calculate dietary risk for those under the age of 6.

Mr. Waxman's bill would impose a separate risk standard—reasonably anticipated to cause cancer and other effects in the case of children. Unlike the negligible risk standard of H.R. 1627, or the current safety standard under Section 408 of the Food, Drug and Cosmetic Act, Mr. Waxman's bill would again impose a zero risk standard.

Indeed, the "reasonably anticipated to cause" standard has been interpreted by EPA in a number of other environmental statutes to foreclose the consideration of exposure or dose. Therefore, this standard would pose the same problems as the Delaney Clause by precluding EPA from establishing pesticide tolerances under a negligible risk standard.

H.R. 1627 already provides EPA with adequate authority to examine all dietary risks associated with pesticide residues, including breast cancer and reproductive effects and to consider the special sensitivity of all major consumer groups, including women. Separate standards for particular disorders, I think, are unnecessary.

I would recognize the ranking minority member, Mr. Waxman, for his opening statement.

Mr. WAXMAN. Thank you very much, Mr. Chairman, for recognizing me, for holding this hearing. I want to apologize to you and to all the participants of this hearing for the delay. Not only did we have a vote on but I was tied up in another meeting dealing with a hospital problem in my district.

Mr. BILIRAKIS. I thought you might have stopped to take a little nap after last night.

Mr. WAXMAN. I wish. I wish. I am looking forward to next week.

I have serious concerns about H.R. 1627. It would repeal basic health standards, create new bureaucratic hurdles for Federal agencies, subordinate health concerns to economic considerations and dramatically diminish the role the Federal Government has in safeguarding our Nation's citizens from pesticide risks. If we assume this bill will pass this subcommittee and the House, the Federal Government simply will no longer be able to help protect consumers from being exposed to a number of pesticides that are known and probable human carcinogens. I obviously strongly disagree with that result but if it happens, H.R. 1627 should, at the very least, give consumers the option and ability to protect themselves.

Individual citizens must have the tools to fend for their families if the Federal Government abandons its traditional role of protecting the public health. That is why the right-to-know provisions in H.R. 1771 are so important. By providing a short, common-sense warning label, we empower consumers who are concerned about unnecessary exposures to dangerous pesticides to protect themselves. H.R. 1771 also recognizes that, at a minimum, we must also adopt a special standard to protect kids from dangerous pesticides. A tolerance should not be issued if EPA reasonably anticipates that a particular pesticide will hurt children.

To ensure that sound science is used in making these determinations, the bill directs EPA to follow the recommendations of the

National Academy of Sciences report on pesticides and chil-
The same common sense test must be applied to pesticides
ose a special risk of breast cancer or reproductive harm for
n. Without this provision, the Bliley-Roberts bill would expose
ns of women to a preventable and reckless danger.
Chairman, we are not asking for a zero risk standard. We
mply saying that we don't feel that the Bliley-Roberts bill is
h protection because it would allow the use of pesticides that
residue in food that offer a special risk to children, and they
llow the use of pesticides that offer special risk to women of
cancer. If we are going to allow that, we ought to recognize
iblic's right to know. If it is going to be a risk, the public
to know about it and be able to decide for themselves if they
o take that risk.
reason the bill, the fundamental bill, the basic bill, the Bliley
so troublesome is it doesn't protect against health risks. It
ealth risks are one thing but economic considerations are an-
Risks will be permitted if the economic considerations are
o outweigh the health risks. That is why we have said, if you
ing to use that standard, use it, but if there is a special prob-
r children, we ought to take precautions there. If there is a
l problem to women because of breast cancer, take special
itions there. And if it is a risk overall, at least let the public
about it.
will be offering our bill as an amendment. This hearing, we
will flesh out the issues and allow witnesses to testify who
hese special concerns. I certainly want to work with you and
her members of the committee to get a responsible piece of
tion through. We have been trying to do that for a number
rs now. But I do not feel that the Bliley-Roberts bill is a re-
ble one. I think it puts the public at great risk unnecessarily.
nk you for calling this hearing.
BILIRAKIS. And I thank you, sir.
Coburn is recognized for an opening statement.
COBURN. Mr. Chairman, I don't have an opening statement.
BILIRAKIS. I thank the gentleman. Mr. Stupak.
STUPAK. Mr. Chairman, thank you for calling this hearing.
d like to yield my time to my colleague, Sherrod Brown, who
be in a markup here, so I'd like to pass and yield to him.
BILIRAKIS. I have no problem with that——
WAXMAN. Mr. Chairman, would you just allow me to say I
to run down to another hearing, just to make an opening
ient. I'll be right back.
BILIRAKIS. Sure.
BROWN. Mr. Chairman, thank you, and Mr. Stupak. I just
d to enter my statement in the record. I have a markup in
ational Affairs, and I'll yield my time back to Mr. Stupak,
uld like to enter my statement.
BILIRAKIS. We're playing games this morning, I guess, but
ve to do that to stay awake.
STUPAK. I have nothing further, Mr. Chairman.
BILIRAKIS. Nothing further? Doctor—I don't think I have to
n, do I, that we have been up all night voting? I think if you
ok at us, you can see that.

Dr. Norwood.

Mr. NORWOOD. Mr. Chairman, I ask unanimous consent to enter my remarks for the record, please.

Mr. BILIRAKIS. Without objection, all members' remarks will be made a part of the record.

[The prepared statement of Hon. Sherrod Brown follows:]

PREPARED STATEMENT OF HON. SHERROD BROWN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Thank you, Mr. Chairman. I am pleased to say that when I go to the supermarket to shop for myself and my two daughters, I can buy apples, or soup, or any of the thousands of foods currently protected by our food safety laws, *all through the year.* No one can argue that Americans have the safest, most abundant, and affordable food supply in the world. But there is room for improvement.

To maintain the quality, quantity, and price of our food supply, it is necessary to reconsider the way we weigh the relative risks and benefits of using pesticides. At the same time, I believe we must rely on a *single, health-based standard* when determining tolerance levels of pesticides on all foods. We *can* be flexible without compromising our obligation to protect public health and safety.

While science has become too sophisticated to reasonably adhere to the "zero-risk" standard of the Delaney Clause, I believe we can develop a standard for all foods that promotes flexibility, while at the same time maintaining the integrity of our food supply. A standard like this will serve as a benchmark for EPA as they weigh the balance of benefits in determining tolerances. Smart government allows itself to consider the balance of influence of all things, and I believe food safety should permit the wisdom of this analysis.

However, as the committee continues this discussion considering the inclusion of scientific data in the determination of pesticide tolerance levels, I want to make sure that our most vulnerable consumers are afforded special protections. Infant's and children's diets include concentrations of foods that are not present in adult diets. This fact, together with the knowledge that growing bodies are vulnerable to the chemicals found in pesticides, demands our attention. Consistent with the report issued by the National Academy of Science, I urge the committee to ensure adequate protections for infants and children.

Any way you look at it, a safe, economical and abundant food supply is in the best interest of everyone. A safe food supply means we can eat tomatoes, and watermelon and strawberries this summer until our heart's content. An economical food supply means *everyone* can afford to eat these foods. And finally, an abundant food supply means that we will never go without. All of these things amount to consumer protections that I believe are imperative to maintain consumer confidence.

With the proper revisions to today's food safety laws, we can improve on the value of our food supply and preserve consumer confidence. A quality food supply gives us children who can learn in school, it gives us a productive work force and it gives us a healthy public. I appreciate the work we are doing here today and look forward to hearing from our witnesses.

Mr. BILIRAKIS. Doctor—you have no other opening statement, Dr. Norwood?

Mr. NORWOOD. No, sir.

Mr. BILIRAKIS. Dr. Ganske?

Mr. GANSKE. Thank you, Mr. Chairman. I'll be brief. I have an interest in the testimony, some of the testimony—all of the testimony we are going to hear today.

My mother had breast cancer when she was 23. I have—consequently all of my sisters have an increased risk for breast cancer and over the course of my medical practice both in general surgery and plastic surgery I took care of a large number of ladies who had breast cancer, and all of us who have children and have had the opportunity of taking care of children are concerned about these issues and so I look forward very much to some of the testimony. Thank you.

Mr. BILIRAKIS. I thank the gentleman. His time has expired.

I would ask the panelists to come forward as I call your name. Ms. Nancy Chuda of Los Angeles, California; Dr. Philip Landrigan, Professor and Chair, Department of Community Medicine, Mount Sinai Medical Center; Dr. Mary Wolff, Mount Sinai Medical Center; Mr. Robert Eichler, from Portage, Michigan; Dr. J. Routt Reigart representing the American Academy of Pediatrics; Mr. Edward Hopkins, Environmental Policy Director with the Citizens Action here in Washington; and Ms. Caroline Smith-DeWaal, Director, Food Safety Program, Center for Science in the Public Interest again here in Washington.

All of your prepared statements of course, as you know, are part of the record. I would ask you to keep your oral statements within the 5-minute rule, and possibly during the round of questioning if there are other points you may wish to make you'll have an opportunity to do so at that time.

Let's start out with Ms. Chuda.

STATEMENTS OF NANCY GOULD CHUDA, ON BEHALF OF COLETTE CHUDA ENVIRONMENTAL FUND AND CHILDREN'S HEALTH ENVIRONMENTAL COALITION; PHILIP J. LANDRIGAN, CHAIRMAN, DEPARTMENT OF COMMUNITY MEDICINE, MOUNT SINAI MEDICAL CENTER; BOB EICHLER, PORTAGE, MI; J. ROUTT REIGART, ON BEHALF OF AMERICAN ACADEMY OF PEDIATRICS; MARY S. WOLFF, MOUNT SINAI SCHOOL OF MEDICINE; EDWARD HOPKINS, ENVIRONMENTAL POLICY DIRECTOR, CITIZENS ACTION; AND CAROLINE SMITH-DeWAAL, DIRECTOR, FOOD SAFETY PROGRAM, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Ms. CHUDA. Good afternoon, Mr. Chairman, and members of the subcommittee. I am Nancy Gould Chuda, Chair of the Colette Chuda Environmental Fund and Executive Director of the Children's Health Environmental Coalition. My husband, James, is the Co-Chair, and I appreciate this opportunity you have afforded us today.

I am here to testify on behalf of children, too young, too vulnerable to protect themselves from the daily onslaught of chemical toxins to which they are being exposed.

H.R. 1627 ignores what the NAS told us 2 years ago in its report. This report found that the current regulatory system fails to give special consideration to the unique vulnerabilities of infants and children regarding pesticide exposures. It also fails to acknowledge the cumulative and synergistic impacts of multiple exposures.

We know that there are 750 million pounds of 20,000 different pesticidal potions used in America annually and currently regulations allow for 40 pesticides in carrots, 67 in strawberries, and 82 in grapes. These are the typical foods that children consume in great quantities. H.R. 1627 enshrines into law that if a pesticide residue poses a significant risk to the public including children the residue is still allowed if it is said to have a sufficient benefit.

There is no benefit to a government that puts its children at risk. We lost the love and light of our lives when our only child, Colette, died of Wilm's Tumor, a rare, nongenetic form of cancer in April 1991. She was 5 years old. There are no words of comfort that can

be offered, no consolation for the loss of opportunity shared when a child dies.

I believed intuitively that something in the environment had interfaced with her gestational development and after consulting an expert on Wilm's Tumor, I learned that it was possible that something that I had ingested or was exposed to during my pregnancy could have caused her cancer to develop.

In March 1995 a study was published in the American Journal of Epidemiology, "Parental Exposure to Pesticides and Risks of Wilm's Tumor." It stated that environmental exposures may contribute to the development of Wilm's Tumor. The study reveals the highest odds ratio to be among cases diagnosed after 48 months of age for maternal exposure. Colette was exactly 48 months of age when she was diagnosed.

This was our daughter. She is featured on the cover of this month's "E, the Environmental Magazine." and it is because of her and the countless other children whose lives are being lost to cancer that we must make legislative changes now.

When children are stricken with cancer, you fight for their lives. Your heart grows cold at the thought that they might die. The battle you wage is equal to all the world wars that have ever been fought, to see children clinging to their mothers and fathers for life, to gaze into their eyes and see hope dwindling, to feel their confusion when words can no longer be uttered or understood, to watch trust, the very bond that glues them to our hips, slowly slips away—it is at these moments that you wish that you had never been born, never to bear witness to such cruelty. We will never forget her bravery. She taught us not to be afraid to die and it is this flame that burns deep in our hearts that brings us here today to spare you and your children and your grandchildren this intolerable pain.

I am convinced that Colette's death was due to a pesticide exposure and had I known that about the carcinogens she or I were exposed to, I would have had a choice. I could have found safer alternatives.

Two days before she died she looked at us and said, "Mommie, why did this have to happen to me?" I cannot answer her question and to this day Jim and I have only her mission in our hearts and the knowledge that we, the people, will find the answer.

Since her passing 4 years ago not a day goes by when I don't think about what could have caused her cancer and it is for these reasons that we strongly encourage you to support H.R. 1771, The Pesticide Safety and Right to Know Act of 1995.

I praise Congressman Waxman for his continuous efforts and determination to protect our Nation's children. Let us have the choice and the right to know what is in our food and the products we consume. Let us begin with a new trust, one that restores hope in the Government, which currently does not provide for our children with the safeguards they deserve.

I speak for countless parents concerned about these issues who feel helpless and frustrated in not being given the right to know and the freedom to choose.

If we value our children as I know we all do, we must protect them and we must provide for their safety.

Can we take the risk of being wrong?

I urge you to err on the side of caution and I thank you for this opportunity to share with you today, and I'll be pleased to answer any of your questions.

[The prepared statement of Nancy Gould Chuda follows:]

PREPARED STATEMENT OF NANCY GOULD CHUDA, CHAIR, COLETTE CHUDA ENVIRONMENTAL FUND, EXECUTIVE DIRECTOR, CHILDREN'S HEALTH ENVIRONMENTAL COALITION

Good Morning, Mr. Chairman and members of the subcommittee. I am Nancy Gould Chuda, Chair of The Colette Chuda Environmental Fund and Executive Director of the Children's Health Environmental Coalition (√CHEC). My husband James, co-chair of The Colette Chuda Environmental Fund, and I appreciate this opportunity you have provided us.

The Colette Chuda Environmental Fund and its project, The Children's Health Environmental Coalition (√CHEC) are non-profit environmental organizations founded in June 1991. We first established the fund to research the causes of children's cancer in relation to the environment. We then created (√CHEC). This national bipartisan grassroots organization gives parents a unified voice and an opportunity to express their concerns as they relate to the environmental health and safety of their children.

I am here to testify on behalf of our organization and for those who are too young and vulnerable to protect themselves from the daily onslaught of chemical toxins to which they are being exposed.

The pesticide laws that you are considering enacting totally disregard the special needs of children. H.R. 1627, The Food Quality Protection Act of 1995, ignores what The National Academy of Sciences (NAS) told us two years ago, in its report, *Pesticides in the Diets of Infants and Young Children (1993)*. This report found that pesticide tolerances are not based primarily on health considerations, and that the current regulatory system fails to give special consideration to the unique vulnerabilities of infants and children as they relate to pesticide exposures.

H.R. 1627 fails to acknowledge the cumulative and synergistic impact of multiple exposures. This bill does not comply with the NAS findings. In fact, it undercuts protective provisions thus weakening our pesticide laws. If H.R. 1627 is left unamended, Dr. Philip Landrigan, who directed this study, has concluded that "we will by default continue to conduct a massive clinical toxicological trial and our children and their children are the experimental animals."

According to the Academy, "children should be able to eat a healthful diet containing legal residues without encroaching on safety margins." Any legislation that is passed should require an explicit finding that exposure to legal limits is safe for infants and children. This bill does not allow considerations of multiple pesticides, and fails to consider the threats posed by so-called "inert" ingredients.

Children are unique. They consume large amounts of fruit and vegetables, significantly more proportionally than adults, in relation to their size. These foods are all common vehicles for pesticide exposure. The average one year old drinks 21 times more apple juice, 11 times more grape juice and 2.5 times more water than the average adult. Children also eat as much as seven times more grapes, strawberries, bananas, apples, pears, carrots and broccoli. What we are finding out about children is that they are essentially developing organisms whose biological systems are just forming and far more vulnerable to the toxic residue they ingest in their food than their adult counterparts.

We know that 750 million pounds of some 20,000 different pesticidal potions are poured over the American landscape annually and current regulations legally allow for 40 pesticides in carrots, 67 in strawberries and 82 in grapes.

These are the typical foods children consume. H.R. 1627 enshrines into law that even if a pesticide residue poses a significant risk to the public, children not withstanding, the residue is allowed if it is said to have "sufficient benefits."

There is no benefit to a nation that allows its most vulnerable members of society to be at risk.

And at risk they are. Every day, the NAS study reported, about 1.3 percent of the nation's two-year-olds, or about 50,000 children, receive a dose of five pesticides in excess of the EPA's acceptable limits. A related study by the Environmental Working Group (EWG), *Pesticides in Children's Food (1993)*, documented for the first time the prevalence of multiple residues in single foods. It reported that it is not uncommon for children to eat single piece of fruits or vegetables with 5 or more pesticides on them. The study revealed the severity and imbalance of pesticide expo-

sure early in life and estimated that for the "average child," EPA's "acceptable" lifetime level of risk is exceeded by age one. From birth to age 5, it continued, children bear a disproportionately heavy burden from pesticides in food and water. Yet, the Environmental Protection Agency has never set a tolerance for a pesticide in food specifically to protect infants and children.

In another study released by EWG in February, *Forbidden Fruit: Illegal Pesticides in the U.S. Food Supply (1995)*, it was reported that Americans eat 2 billion pounds of produce contaminated with illegal pesticides each year. Over 90 percent of the violations noted involve two kinds of illegal pesticides: no-tolerancy violations, where the pesticide is found on a crop even though the allowable level for the pesticide on that crop is zero; and over-tolerance violation, where the amount of the pesticide found exceeds the legal limit for that crop.

As consumers, we enter the marketplace everyday trusting that what we buy and share with our families and friends is safe. We expect that our hard-earned tax dollars are providing for protections that will safeguard us and especially our children. As citizens of this country we deserve that right. As lawmakers, you must provide us with an opportunity to make the choices that will support the health and safety of our families.

I would not be sitting here today if it weren't by the grace of God and the tragedy my husband and I were meant to face. There are no words of comfort that can be offered, no consolation for the loss of opportunity shared, when a child dies.

We lost the love and the light from our lives in April, 1991, when our only child, Collette, died of Wilm's Tumor, a rare non-genetic form of cancer and one of the most common abdominal childhood malignancies. She was five years old.

As her mother, I believed intuitively that something in the environment had interfaced with her gestational development. Later I learned, after consulting an expert on Wilm's tumor, that it was possible that something I ingested or was exposed to in my environment during my time of pregnancy could have triggered the destruct mission that caused her cancer to later develop. And in March 1995, I received a newly released study that supports my belief about my pesticide exposure and the development of Wilms' Tumor in my daughter. The study: *Parental Exposure to Pesticides and Risk of Wilms' Tumor in Brazil (1995)*, published in the American Journal of Epidemiology, states that environmental exposures may contribute to the development of Wilms' tumor. The most important finding related to my exposure and Colette's cancer concerns the interactions between parental pesticide use before the pregnancy and the age of the child at diagnosis of Wilms' tumor. The study revealed the highest odds ratios to be among cases diagnosed after 48 months of age, for maternal exposure. Colette was diagnosed when she was four years old—at exactly 48 months of age.

Additionally, the study indicated that "the effects of pesticides could be mediated by mutations in germ cells, by exposure of the fetus in utero, or by exposure after birth from residues present in breast milk, in foods, in the home, or in the surrounding environment."

Another study released last fall, *Handle With Care: Children and Environmental Carcinogens (1994)* reviews what is known about childhood exposures to carcinogens and examined information on nearly 400 cancer-causing chemicals, some of which are present in our homes and schools. This report, by The Natural Resources Defense Council, reveals that "the overall incidence of childhood cancer increased 10.8 per cent between 1973 and 1990. Brain/nervous system cancer and acute lymphocytic leukemia increased 32.6 and 27.4 percent respectively during those years." Cancer, the council reports, is now the number one disease killer of children from late infancy through early adulthood.

Additional findings determined that certain pesticides in foods can be reasonably anticipated to cause many health problems associated with children: infertility, reproductive, developmental, endocrine, neurobehavioral, respiratory and immune system function, and cancer.

The study emphasized that children are not simply small adults. "They are growing, and developing and are thus more vulnerable to exposure from environmental toxins that include certain pesticides in food due to their physiology and their behavior. Scientific data which is derived entirely from adults or from testing on adult animals is not an accurate way to predict how a child will react to chemical compounds."

More evidence related to pesticides and the development of childhood cancer was reported in *Parental Occupational Exposures and Risk of Childhood Cancer: A Review (1991)*, a study published in the American Journal of Industrial Medicine. This report notes there is a "strong correlation and association between parent occupational exposures to chemicals found in pesticides and the risk in our nation of childhood malignancy."

This growing body of scientific evidence makes it clearer than ever before in our nation's history that children are being exposed to a host of life-threatening toxic chemicals, many of which are ubiquitous in their environment. A toxicologist at the National Institute of Environmental Health Service recently underscorod the grave nature of the problem we face. "It is estimated that a complete health hazard assessment is available for less than 1 percent of commercial chemicals and toxicity information is totally unavailable for 80 percent," he said. "Even if all the world's scientists directed their attention to toxicity testing by traditional methods, we would be unable to test the chemicals which are covered by existing legislation."

In light of this dilemma, to ensure our children's good health, the protocols for scientific research need to be changed. And concurrently, what you as legislators need to do in order to safeguard our children's health right now, is to take every possible measure to guarantee our children's protection against environmental toxic exposures.

Many years ago, I had the fortunate opportunity to meet one of our county's greatest statesman, The Honorable James Delaney. We are pictured together here in Key Biscayne, Florida in 1973. When I asked the then retired Congressman what prompted him to write the Delaney Clause, he told me that he had lost his beloved wife to cancer and that he wanted to provide a law that would protect Americans from being exposed to cancer-causing chemicals. In his day, there was no such thing as an acceptable risk. Little did I realize then that my future husband and I would face the tragedy of losing our five year old daughter to the same deadly disease.

The Delaney Clause of the Food, Drug and Cosmetic Act (1958) has been the only bright spot in the flawed regulatory regime. The clause prohibits any food additive in processed food that "induces cancer in man or animal."

However, since its enactment, the provisions of the Delaney Clause prohibiting carcinogens in processed foods have largely been ignored with respect to pesticides. The promise of the Delaney Clause remains unfulfilled. The essential premise of the clause is simple: what we understand best about carcinogens is the limited extent of our knowledge. The 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 routinely exposed to carcinogens in their daily diet.

This was our daughter. She is featured on the cover of the June issue of *E—The Environmental Magazine*. It is because of her and the countless other children whose lives are being lost to cancer that we must make legislative changes now to ensure the future of generations to come.

I would like to share with you now what parents who have lost children tragically to cancer have learned, and what you as legislators and policy makers need to know.

When children are stricken with cancer you fight for their lives. Your heart grows cold at the thought that they might die. The battle you wage is equal to all the world wars that have every been fought. To see children clinging to their mother and father for life, to gaze into their eyes and see hope dwindling... to feel their confusion when words can no longer be uttered or understood... to watch as trust, the very bond that glues them to our hips, slowly slips away... it is at these moments that you wish you had never been born, never to bear witness to such cruelty.

We all have our wounds. As Colette's parents, we will never forget her bravery. She taught us not to be afraid to die. She proved to us that unconditional love lasts forever. It is this flame that burns deep in our hearts that brings us here today.

A mother's intuition never dies nor does it fade away. Supported now by new scientific evidence, referred to earlier in my testimony, I am convinced that Colette's death was due to a pesticide exposure. *Had I known then the carcinogens that she or I were exposed to, I would have had a choice... I could have found alternatives.*

I would like to share an intimate moment in our lives. Two days before Colette died, as she lay in her bed, she looked at me intently and asked, "Mommy, why did this have to happen to me? As her mother, I could not answer her question and to this day Jim and I have only her mission in our hearts and the hope that we the people can make a difference *and we will.*

Since the passing of Colette four years ago, not a day goes by that I don't think about her and what could have caused her cancer.

How can it be that this government has forgotten about its children? How can you as legislators support a Contract for America that does not consider their environmental health and well being? When we talk about health care reform we have a responsibility to include prevention.

I speak not only for myself and my husband, but on behalf of the countless thousands of mothers and others who have contacted me since the death of Colette and the start of our campaign in 1991. All are concerned about these issues and feel

helpless and frustrated in not being given the right to know and the freedom to choose as it relates to the purchases of food affecting the health of their children.

As we review the laws of the land which are written today, nowhere is it written that children have the right to a safe a clean environment. Nowhere is it written that children are protected from man-made chemicals that cause cancer; nowhere is it written that the parents of these children and other citizens of this country have the right to know what is the food they eat, the water they drink and the air they breathe.

It is for these reasons that we strongly encourage you to support H.R. 1771, the Pesticide Safety and Right-to-Know Act of 1995. I praise you Congressman Waxman for your continuous efforts and determination to protect our nation's children.

Let us have the choice and the right to know what is in our food and the products we consume. Let us begin with a new trust, a way in which we can restore hope in our government which sadly is not providing us nor our children with the safeguards we deserve.

You have the opportunity today to start righting this wrong by "amending" H.R. 1627, The Food Quality Protection Act of 1995, and supporting The Pesticide Safety and Right-to-Know Act.

We urge you to err on the side of caution and as responsible legislators do what you intuitively know in your heart is the right thing. In addition, we encourage you to increase your support for environmental health research.

If we value the future of human life, as I know we all do, we must protect it. If we value the future of human life, as I know we all do, we must provide for its safety. If we value the future of human life we must honor its existence.

We must honor our children for they are the cornerstones of our lives and our nation. They are the future of America.

I thank you for this opportunity to share with you today and would be pleased to answer any questions.

Mr. BILIRAKIS. Thank you, Ms. Chuda. I know it was very difficult for you. Thank you for having the courage to present your testimony.

Dr. Landrigan.

STATEMENT OF PHILIP J. LANDRIGAN

Mr. LANDRIGAN. Thank you, Mr. Chairman. I am Philip Landrigan. I am a pediatrician and Professor of Pediatrics in Community Medicine at Mount Sinai in New York. I am here today because I was Chair of the Committee at the National Academy of Sciences that in June, 1993, issued this report, "Pesticides in the Diets of Infants and Children." What I would like to do is take a moment or two to summarize with you the major conclusions of that report and then compare those conclusions to the two bills that are before you now—H.R. 1627 and H.R. 1771.

Well, one major set of conclusions that we reached which will be no surprise to anybody who has ever been around children is that children are fundamentally different from adults and we took a great deal of time to detail precisely how children differ from adults.

First, of course, they are growing and developing—the nervous systems, the immune systems, the reproductive organs of children are undergoing development all through childhood. Because vital connections are being laid down, these developmental processes are highly susceptible to being disrupted by any environmental toxins or, particularly in the case of the nervous system, if damage is done in early childhood, if the nervous system is injured during critical windows of vulnerability, it is likely that the injury will be life-long. The nervous system does not have very much capacity to repair itself once injury has been sustained.

Second, children are very different from adults in their patterns exposure, in their diets and their patterns of exposure. For example, the average child in the first 6 months of life drinks 7 times much water, pound for pound, as do most adults. They eat many mes more fruits and vegetables pound for pound than do adults. What this means therefore is that any toxins that are present, ny pesticides or other toxins that are present in those particular ods that comprise so great a part of children's diets, will result proportionally very heavy exposures to kids.

Because children are young, because they have many more years f life ahead of them than an adult, any diseases that are triggered, initiated by exposures in those first few years of life will ave 6 or 7 decades in which to play out. By contrast, we have ewer years ahead of us and any toxic exposures that we sustain midlife are less likely than similar exposures sustained in early hildhood to produce toxic effects.

It was for all these reasons, in recognition of the very enhanced xposures and the greater vulnerability of children as compared to dults that our committee at the National Academy of Sciences recommended very strongly that the Environmental Protection Agency nd the other regulatory agencies that are involved with pesticides odify the procedures that they use in setting pesticide tolerances—this is on page 8 of the Executive Summary—so that the tandards be based principally on considerations of protecting the public health.

Pesticide tolerances are currently set through a balancing proc-ss, health considerations are traded off against economic and agri-ultural considerations. We urge that primacy be given to the pro-ection of public health in the setting of standards, that the balance e tilted, in other words, in favor of children.

We made a series of specific recommendations for better data col-ection and I was pleased to see that several of those provisions ere echoed in H.R. 1627 for better food surveys over sampling of ods eaten by children, surveys of residues, better toxicity testing rocedures—those are clear strengths of H.R. 1627 over current rocedures.

However, I was very, very much concerned by the decision that as obviously been made by the framers of H.R. 1627 to quietly do way with the Delaney Clause. Now the Delaney Clause is not a erfect instrument. Anybody who has thought about pesticides nows that. It is an absolute instrument. It does not embody cur-ent state-of-the-art thinking and quantitative risk assessment.

You have taken testimony previously. I was here on February nd. John Graham, my colleague from Harvard, talked about new levelopments in risk assessment, and it is clear that the Delaney Clause does not embody those, but the thing is if you are going to hrow away Delaney it's got to be replaced by something that is at east as protective of children as the Delaney Clause is. For all its mperfections the Delaney Clause has been a bulwark which for the ast 40 years or so has succeeded in protecting children against the nost hazardous pesticides in the diet and it is not something that hould be let go lightly.

As a pediatrician I am very worried about the negligible risk tandard which is put forth in H.R. 1627. I am very much con-

cerned that it will allow continued trading off of economic against health considerations in setting tolerances, and I would urge you to go with H.R. 1771 and not to support H.R. 1627. Thank you.

[The prepared statement of Philip J. Landrigan follows:]

PREPARED STATEMENT OF PHILIP LANDRIGAN, M.D., M.SC., PROFESSOR AND CHAIRMAN, DEPARTMENT OF COMMUNITY MEDICINE, THE MOUNT SINAI MEDICAL CENTER

Mr. Chairman and members of the subcommittee. Thank you very much for having invited me to testify before you teday on the issue of protection of infants and children against pesticides in the diet and to comment specifically on H.R. 1771, the Pesticide Safety and Right-to-Know Act of 1995, as well as on H.R. 1627, the Food Quality Protection Act of 1995.

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 Hazards of the American Academy of Pediatrics. From 1988 through June 1993 I served as Chair of the National Research Council (NRC) Committee on Pesticides in the Diets of Infants and Children. This Committee issued its unanimous final report in June 1993.

The NRC Report on Pesticides and Children

I would like to begin my testimony today by summarizing the major findings of the 1993 NRC Report on Pesticides in the Diets of Infants and Children.

The NRC report concluded that the federal regulatory system currently in place in the United States does not adequately protect children against pesticides in the diet. The federal 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. It fails to recognize that children differ greatly from adults not only in their size but also in their metabolism and in the food they eat.

A fundamental tenet of pediatric medicine is that children are not just little adults. They are in many respects truly different. The NRC committee noted the following unique features of children:

- Children eat different foods from adults and they eat them differently. Children in the first 6 months of life drink 7 times as much water pound-per-pound as the average adult. The average one-year-old drinks 21 times more apple juice and 11 times more grape juice and eats 2-7 times more grapes, bananas, pears, carrots and broccoli as the average adult. In consequence of their unusual diets, children have substantially heavier exposures than adults to any pesticides that are present in their foods. Every day thousands of American children are exposed to pesticides in food, milk and drinking water,
- Children's metabolic pathways, especially in the first months after birth, are immature compared to those of adults. As a consequence of this biochemical immaturity, children's ability to metabolize, detoxify and excrete certain toxins is different from that of adults. In some instances, children are actually better able than adults to deal with environmental toxins. More commonly, however, they are less well able than adults to deal with toxic chemicals and thus are more vulnerable to them.
- Children are undergoing rapid growth and development, and their delicate developmental processes are easily disrupted. Many organ systems in young children particularly the nervous system, the immune system and the reproductive organs, undergo very rapid growth and development in the first months and years of life. Structures are being developed and vital connections established. Indeed development of the nervous system continues all through childhood, as is evidenced by the fact that children continue progressively to acquire new skills as they grow and develop: crawling, walking, talking, reading, and writing. The nervous system in not well able to repair any structural damage that is caused by environmental toxins. Thus, if cells in the developing brain are destroyed by pesticides, or if vital connections between nerve cells fail to form, there is high risk that the resulting neurobehavioral dysfunction will be permanent and irreversible. The consequences can be loss of intelligence and alteration of normal behavior.
- Because children have more future years of life ahead of them than do most adults, they have more time to develop any chronic diseases that may be triggerod by early environmental exposures. Many diseases that are triggered by

pesticides and other toxins in the environment require decades to develop. Examples include mesothelioma caused by exposure to asbestos, leukemia caused by benzene, breast cancer caused by DDT, and possibly some chronic neurologic diseases such as Parkinson's disease and Alzheimer's disease that nay be caused by exposures to environmental neurotoxins. Many of those diseases are now thought to be the products of multistage processes within the body's cells that require many years to evolve from earliest initiation to actual manifestation of illness. In this context toxic exposures sustained early in life appear more likely to lead to disease than the same exposures encountered later in life.

To better protect the health of America's infants and children, the NRC Committee recommended strongly that the federal government take cognizance of children's unique vulnerabilities and exposures and revamp scientific and regulatory procedures for controlling pesticide residues in children's diets. The Committee also recommended that the regulatory agencies adopt a new method of risk assessment that will more accurately gauge the population at risk. And it urged 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 exchange their children's diets to avoid certain foods. On the contrary, we emphasized that 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 the foods eaten by all of our infants and children are safe.

Tolerances—defined as the levels of pesticide residues permitted on or in foods when they leave the farm—constitute the only legal mechanism for regulating pesticide residues in foods.

A central recommendation of the NRC Committee was that the federal government must have as its clear goal the setting of tolerances that more fully protect human health, particularly the health of infants and children. The Committee stated that children must be able at all times to eat a diet that is safe and healthful.

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 affects 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 affects 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 a further rationale for the NRC recommendation of an additional 10-fold safety factor.

H.R. 1771, The Pesticide Safety and Right to Know Act of 1995.

I commend you, Mr. Waxman, for having introduced H.R. 1771, the Pesticide Safety and Right to Know Act of 1995. In particular, I applaud you for having included in this bill section 3 on the Protection of Children which states

> "The Administrator [of the Environmental Protection Agency] shall before prescribing a tolerance for a pesticide chemical under this section, determine in writing whether dietary exposure to the pesticide chemical under the tolerance being prescribed for the pesticide chemical is reasonably anticipated to cause cancer, damage to the developing neurological, immune, or reproductive systems or other serious adverse health effects in any child. The Administrator *may not* prescribe a tolerance for a pesticide chemical if the Administrator determines that dietary exposure to the pesticide chemical under such tolerance is reasonably anticipated to cause such effects in any child."

This straightforward, sensible and unambiguous proposal provides clear guide to the federal regulatory agencies. It places protection of our nation's children, and thus of America's future as the clear goal of the national regulatory agenda. This

proposal is consistent with the major recommendations of the NRC report. This proposal indicates that the over-riding purpose of the pesticide regulatory program in the United States is protection of human health, and in particular the health of the most vulnerable members of our society.

H.R. 1627 Amendments to the Federal Insecticide, Fungicide and Rodenticide Act, (FIFRA) the Food Quality Protection Act of 1995.

The amendments to FIFRA that have been proposed under H.R. 1627 are not protective of the health of children. These proposals are not consistent with the main conclusions and recommendations of the report of the NRC Committee on Pesticides in the Diets of Infants and Children,

Instead of stating unambiguously that the primary goal of pesticide regulation is to protect human health H.R. 1627 directs the federal agencies merely to "consider" the aspects of pesticides on the health of children. Under subparagraph G, p59-60, H.R. 1627 permits the federal agencies to balance the protection of children's health against short-term economic considerations in setting tolerances for pesticides.

H.R. 1627 talks at great length about the processes that the federal agencies should use to set pesticide standards. But H.R. 1627 does not give primacy to the protection of our children's health.

And finally H.R. 1627 quietly abolishes the protection to children's health that for the past four decades has been embodied in the Delaney Clause. The Delaney Clause unambiguously and unequivocally bans cancer-causing pesticides that concentrate in processed foods. H.R. 1627 would abolish this straight-forward approach to the protection of our children and replace it with an ambiguous "negligible risk" standard, which would permit EPA to balance children's health against economic and other factors in regulating pesticides.

The Delaney Clause is not a perfect instrument. It does not embody the latest developments in quantitative risk assessment. But despite its shortcomings, the Delaney Clause is a powerful piece of legislation that has served to protect several generations of American children against carcinogenic pesticides. As a pediatrician, I would be willing to see the Delaney Clause removed from FIFRA, if it were replaced by language directing the federal agencies to employ state-of-the-art science to provide clear protection for America's children against toxic pesticides. But in my opinion, the dismemberment of the Delaney Clause proposed in H.R. 1627 is wrong. It should not be enacted into law. It is not health-based. H.R. 1627 protects pesticides, not children.

Conclusion. In summary, Mr. Chairman, infants and children in the United States are heavily and regularly exposed to pesticides in their diets. These pesticides include compounds that have been demonstrated to be carcinogenic, neurotoxic, toxic to the immune system and toxic to the reproductive organs. The federal regulatory systems currently in place do not provide adequate protection to our infants and children against these residues of pesticides.

The incidence of cancer in America's children is increasing. Each year for the past 20 years the incidence of the two most common forms of childhood cancer—leukemia and brain cancer—has increased in the United States. Death rates from these tumors are down, because of advances in pediatric therapy, but incidence is up. For acute lymphocyte leukemia, the most common form of leukemia among children, the cumulative increase in incidence rate over the past 20 years has been 20 per cent. I do not know whether pesticide exposure is responsible in part for these increases in childhood cancer. However, prudence suggests that the widespread exposure of our children to carcinogenic and other toxic chemicals cannot be good for their health.

The legislation that you have proposed, H.R. 1771, represents an important step to strengthen existing federal pesticide regulation in the United States. It will provide strong protections for the health of all of America's children. By contrast, H.R. 1627 is bad legislation. It will perpetuate the current inadequately controlled exposure of children to pesticides in their diets and indeed through its abolition of the Delaney Clause, H.R. 1627 will likely worsen our children's exposure to pesticides.

The future of our nation depends upon our children. Our children are the weakest and most vulnerable members of our society, but they are the future of our society. If our nation is to survive strong into the next century, it is not we, but rather it will be our children who will carry on. We have a responsibility to our children. We have a responsibility to protect their health to give them childhoods that are free of preventable disease and free of toxic exposures. The provisions that you have outlined in H.R. 1771 will achieve these goals. I applaud you for your courage and for your vision in having introduced this legislation.

I shall be pleased to answer any questions.

Thank you.

Mr. BILIRAKIS. Thank you very much, doctor. Mr. Eichler.

STATEMENT OF BOB EICHLER

Mr. EICHLER. Mr. Chairman and distinguished members of the committee, thank you for the opportunity to testify today. I am Bob Eichler, resident of the city of Portage, Michigan, and the father of two teenage daughters. I have lived through the complexities of parenthood for nearly 20 years. I am here today as a consumer of foods that young children eat, not as an expert on pesticides.

My wife and I have been in the child care business since the 1970's. We are actively involved in the Southwestern Michigan Association for the Education of Young Children. Along with this, I am currently a consultant for Child Care Resources, an organization offering comprehensive information and services in the area of child care in southwestern Michigan.

I am concerned about knowing if dangerous pesticides are on the foods we eat. I would like to be made aware if known or probable carcinogens are present on this food. This would help aid our selection of certain foods for my family and for the children in our care.

When you were a little boy or a girl, you took a delicious red apple or peach from the refrigerator and your mother or father said, don't forget to wash it. Did you always? Did you as a child worry that not washing it might harm you? Did you realize that even if you did wash it, you might not get the pesticides off? Thank goodness for parents and other adults protecting children.

Young children eat less food overall but often consume large quantities of certain foods. I know we feed young children a great deal of fresh fruits and vegetables. Knowledge of pesticides through labeling would aid us in determining which fruits or vegetables we would select.

I was in the grocery store this past weekend and saw some dried apricots. I noticed it said "Turkish Apricots, contains sulfur dioxide." I had no idea if sulfur dioxide was a preservative, a pesticide or a flavor enhancer. I asked a clerk and he informed me that sulfur dioxide was a color enhancer and that some people were allergic to it. That rung a bell in my head.

I went home, looked up sulfur to be an ingredient in gun powder, rubber vulcanization and insecticides. This inspired me to pull out my nutrition file and I saw a brochure on sulfites. Here, I learned that sulfites not only have caused severe reactions in some people and problems with asthmatics but it has actually been linked to several deaths. That is pretty serious for just adding color to some foods.

The point here is that labeling can help people make the choice. Remember, in my case, we buy food not only for ourselves but for other people's children. For us, just having the knowledge at our purchase point could help us to decide if we want a particular food or not.

I come here today not as a liberal or a conservative, a Democrat or a Republican but as a realist. Every one of us has probably come in contact with or known someone who has had a problem with pollution or pesticides.

I have a friend who built a home in the 1960's. By 1990, their drinking water in their well was determined too polluted to

consume due to nearby farm chemicals. Chemicals used in only the last century have already got down that far into the earth.

I grew up in Berrien County, Michigan, the heart of the fruit belt. My grandparents owned a fruit farm and helped create a local fruit exchange. As a young boy I picked several fruits and I have empathy with those who are involved with food production. At the same time, recording the use of pesticides at the very least would help us determine where future problems could be averted.

I have another friend who works as a veterinarian's assistant in a clinic and has seen several animals who have been diagnosed with chemical poisoning due to eating pesticides off treated lawns.

Something has to be done to control known and probable carcinogenic pesticides. At the very least, labeling of products would help the consumer make purchasing decisions. It would seem even to the layman the most common sense thing to do.

Thank you again, committee members, for giving me this opportunity to speak up for the voice of today's children and securing a healthy diet for the present and future existence in our world.

Mr. BILIRAKIS. Thank you, Mr. Eichler.

Dr. Reigart.

STATEMENT OF J. ROUTT REIGART

Mr. REIGART. Mr. Chairman, members of the subcommittee, my name is Routt Reigart. I am a professor of pediatrics at the Medical University of South Carolina where I am involved in the practice of general pediatrics and environmental medicine. I am chairperson of the Committee on Environmental Health of the American Academy of Pediatrics. I come to speak to you today as a representative of the more than 48,000 members of the American Academy of Pediatrics.

Since the American Academy of Pediatrics has not officially taken a position on H.R. 1627, my testimony will focus primarily on the principles used by the academy to judge such legislation. I believe, and I think all of you will agree, that H.R. 1627 falls far short of meeting these requirements for Academy support.

Most of the members of the Academy of Pediatrics are practicing physicians who care for children and counsel parents. Most know a great deal about infant and childhood nutrition. In this context, they expect parents and specialists in risk assessment to provide them with adequate information about the risks of pesticides and other chemicals in food to allow them to make appropriate recommendations to their parents. They would like to be able to say, without qualification, your infant or child should eat a diet rich in fruits and vegetables.

Pediatricians also should be able to make several additional affirmative statements. Pesticides used on our food have been tested for safety to infants and children. The risk assessment process has taken into account the difference in children's diets, including diet selection and higher caloric intake. The risk assessment has taken into account the differences in the way children absorb, metabolize, store and clear chemicals and other toxins from their bodies. The risk assessment has taken into account special susceptibility to injury of developing organ systems, particularly the nervous system, endocrine, lung and immune systems of infants and children.

The use of pesticides is regulated and regulations are enforced to nsure that pesticides are used in a safe and proper fashion.

During the several years I have worked with the Committee on nvironmental Health in the Academy of Pediatrics, there has een dramatic shift in the levels of concern with various end points injury. Longstanding concerns about carcinogens in our diet re- ain of interest to the public and pediatricians. However, there as been a marked increase in the understanding of noncancer ndpoints.

We have become increasingly concerned that many children may e suffering significant neurologic impairment, alteration of endo- rine function and hormonally derived behaviors and perhaps im- une suppression. Perhaps the most primary dictum in medicine s a Latin phrase that translates, "First do no harm." It reminds hysicians that it is often possible, with the best intentions, to at- empt an intervention or therapy and subsequently find out that uch therapy did more harm than good. This usually occurs when ve are insufficiently cautious in our prior testing of the new inter- ention for safety while focusing on apparent benefit.

The use of pesticides and setting of tolerances without sufficient onsideration of the risk to children, which has been the routine ractice in the past, clearly violates this dictum and will inevitably ead to harm to children.

The Academy of Pediatrics strongly supports strong health-based andards for tolerance setting for pesticides at the actual levels to hich children may be exposed. Tolerances should ensure that the ctual foods eaten by children at the actual levels of intake are safe r them. Again, the principle is, first do no harm. Whatever the leged benefit of exposing a child to a pesticide, such benefit ould not be obtained by impairing the health of our children.

It is well to consider issues of responsibility and credibility. It is early the responsibility of manufacturers, formulators and appli- tors of pesticides and the government to ensure that our food is afe for our children. If this responsibility is not clearly met in a edible fashion, our children will suffer.

Many of the actions of the public, including the increasing popu- rity of so-called organically grown foods, reflect a public lack of ust in this process. In other words, the present efforts appear to ack credibility with the public and medical community. This credi- ility will only be gained and trust established by strong efforts to nsure the safety for children of our food supply. It is my own view ased on my own experiences that many families and physicians re very concerned that there is so little information regarding the afety for infants and children of pesticides in our food. This con- ern will only be allayed by strong legislation and careful formula- ion and vigorous enforcement of regulations.

Since children cannot make their own choices in food selection, hey are unwilling victims of any errors we make in the risk as- essment and regulatory process. We owe them the highest level of rotection possible. They deserve the highest level of protection ossible.

Thank you, Mr. Chairman. I will answer any questions.

[The prepared statement of J. Routt Reigart follows:]

PREPARED STATEMENT OF J. ROUTT REIGART, M.D., ON BEHALF OF THE AMERICAN ACADEMY OF PEDIATRICS

My name is Routt Reigart. I am a professor of pediatrics at the Medical University of South Carolina where I am involved in the practice of general pediatrics and environmental medicine. I am the Chairperson of the Committee on Environmental Health of the American Academy of Pediatrics. I come to speak to you today as a representative of the more than 48,000 members of the American Academy of Pediatrics. Most of these members are practicing physicians who care for children and counsel parents on a daily basis. They are familiar with the concepts of risk assessment, but few are experts in performing formal risk assessments. Most know a great deal about infant and childhood nutrition and are comfortable in providing counseling to the parents of their patients regarding appropriate nutritional practices. In this context, they expect experts and specialists in risk assessment to provide to them adequate information about the risks of pesticides and other chemicals in food to allow them to make appropriate recommendations for their patients. They would like to be able to say, without qualification, "Your infant or child should eat a diet rich in fruits and vegetables. You need not be concerned about hazards of pesticides in your selection of fruits and vegetables for your child."

In addition, when asked about the hazards of pesticides in food, pediatricians should be able to make several additional affirmative statements:

1. "Pesticides used on our food have been tested for safety to infants and children."
2. "The risk assessment process has taken into account the differences in children's diets including diet selection and the higher caloric intake of infants relative to their body weight."
3. "The risk assessment process has taken into account the differences in the way children absorb, metabolize, store, and clear chemicals and other toxins from their bodies."
4. "The risk assessment has taken into account special susceptibility to injury of developing organs systems, particularly the developing nervous, endocrine, lung, and immune systems of infants and children."
5. "The use of pesticides is regulated and regulations are enforced to ensure that pesticides are used in a safe and proper fashion."
6. "Foods which are available in the marketplace have been inspected to ensure that they do not contain pesticide residues which exceed approved limits which are based on an appropriate risk assessment process which has taken specifically into account risks to children and infants."

In the several years that I have worked with the Committee on Environmental Health of the Academy of Pediatrics, there has been a dramatic shift in the levels of concern with various end points of injury from pesticides to children. Long standing concerns about carcinogens in our diet remain of interest to the public and pediatricians. However, there has been a marked increase in the understanding of the risk of non-cancer endpoints of chemicals in our environmental and our diet. We have become increasingly concerned that many children may be suffering significant neurologic impairment, alteration of endocrine function and hormonally derived behaviors, and perhaps immune suppression, by exposure of the fetus, infant, and newborn.

Perhaps the most primary dictum in medicine is embodied in the Latin phrase *"Primum non nocere"* which is usually translated "First do no harm". It reminds physicians that it is often possible, with the best intentions, to attempt an intervention or therapy, and subsequently find out that such therapy did more harm than good. This usually occurs only when we are insufficiently cautious in our prior testing of the new intervention for safety, while focusing on the apparent benefit. The use of pesticides and setting of tolerances without sufficient consideration of the risks to children (which has been the routine practice in the past) clearly violates this dictum, and will inevitably lead to harm to children.

The American Academy of Pediatrics strongly supports strong health based standards for tolerance setting for pesticides at the actual levels to which children may be exposed. Consideration in ensuring the health of our children must take into account their diet, metabolism, and special susceptibilities. Tolerances should ensure that the actual foods eaten by children at the actual levels of intake are safe for them. Again, the principle is "first do no harm". Whatever the alleged benefit of exposing a child to pesticides, such benefits should not be obtained by impairing the health of our children.

The American Academy of Pediatrics believes, given the available information on the risks of pesticides in the diet, that it is prudent to recommend that infants and children be provided a diet rich in fruits and vegetables. No known risk from pes-

ticides presently outweighs the benefits of this healthful diet. The Academy of Pediatrics also understands the benefits of pesticides to agriculture and accepts the proposition that it is possible to use pesticides in a fashion which is not hazardous to the health of infants and children. It is not possible to use pesticides in such a fashion without knowledge of the actual risks to infants and children. At the present time it is clear that it is not possible to state that pesticides have been evaluated for safety to children and their special needs.

It is well to consider issues of responsibility and credibility. It is clearly the responsibility of manufacturers, formulators, and applicators of pesticides and the government to ensure that our food is safe for our children. If this responsibility is not clearly met in a credible fashion, our children will suffer. Many of the actions of the public, including the increasing popularity of "organically grown" foods, reflect a public lack of trust in this process. In other words, the present efforts appear to lack credibility with the public and the medical community. This credibility will only be gained and trust established by strong efforts to ensure the safety for children of our food supply It is my own view, based on my own experiences, that many families and physicians are very concerned that there is so little information regarding the safety for infants and children of pesticides in our food. This concern will only be allayed by strong legislation and careful formulation and vigorous enforcement of regulations.

Since children cannot make their own choices in food selection, they are potential unwilling victims of any errors we make in the risk assessment and regulatory processes. We owe them the highest level of protection possible. They deserve the highest level of protection possible.

Mr. BILIRAKIS. Thank you, Doctor.

Dr. Wolff, your opening statement, please.

STATEMENT OF MARY S. WOLFF

Ms. WOLFF. Thank you. I am here in my role as a scientist involved in breast cancer research to support Mr. Waxman's position on H.R. 1771 and I am going to briefly summarize what is already in my statement.

We know that chemicals, a number of chemicals cause breast cancer in animals and there is growing evidence that chemicals cause breast cancer in women as well. And there is further warning in the growing evidence about chemical exposures and how they affect hormonal activity in both humans and animals and this is especially important with respect to breast cancer because we know that it is so strongly related to hormonal factors.

Some of the changes that are seen in this hormonal activity are to cause early puberty in animals, to cause gender modification in women. It has been associated with a shortened—DDT has been associated with a shortened duration of lactation and very recently there has been a report in the scientific journal, Nature, that talks about DDT in the rat and how it is an anti-androgen.

So there is a range of chemical activity that may be very important with respect to breast cancer. In addition, we are aware that breast cancer rates are rising, that they affect millions of women worldwide and that, while we don't know the exact causes, that the environment is indeed involved.

Since there are no known medical means of prevention, it is really essential that we try to follow and take advantage of prevention of exposures that may help ameliorate this disease.

I previously supported Mr. Waxman's bill to regulate hormonal exposures which was a real visionary approach and an issue that was a challenge to both science and policy and that also is suited to the issues we are talking about here today. I think it is especially fitting that we are talking about both children and breast

cancer on the same panel. There is a great deal of interest today in breast cancer research on exposures to young children and young adults and how those may particularly make young women predisposed to breast cancer.

Therefore, I want to support H.R. 1771 and its intention to prevent exposures that may cause this disease.

[The prepared statement of Mary S. Wolff follows:]

PREPARED STATEMENT OF MARY S. WOLFF, PH.D., MOUNT SINAI SCHOOL OF MEDICINE

My name is Mary S. Wolff, Ph.D. I am Professor in the Division of Environmental and Occupational Medicine of the Department of Community Medicine at the Mount Sinai School of Medicine, which is part of the City University of New York. My research in environmental health has centered on quantitating exposures of humans to chemicals that occur in the environment, including air pollutants, pesticides, lead, polycyclic aromatic hydrocarbons, solvents, and halogenated hydrocarbons.

HR 1771 is intended in part to prevent toxic exposures that may be related to breast cancer. I am here to address the importance of environmental chemical exposures to risk of breast cancer. Interest in this issue has arisen partly because of studies in our laboratories and others that have shown a link with breast cancer and DDT exposure. Our published reports have been performed in collaboration with colleagues at Hartford Hospital (Dr. Frank Falck and others),[1] at the New York University institute of Environmental Medicine (Dr. Paolo Toniolo and others),[2] and at the Kaiser Research Institute in California (Dr. Nancy Krieger and others).[3] A number of additional research studies are now underway to extend and confirm these findings.

The search for environmental causes of breast cancer began because of our inability to explain the risk to any large extent. Rates of breast cancer are rising in this country, and neither the underlying causes of these diseases nor the reason for the rising rates are known. We know that environment is somehow related to risk, because of vast geographic differences in rates, for example. We also know that for breast cancer, reproductive hormones are a major contributor.

Attention has been focussed on environmental chemicals including pesticides and plasticizers and their potention contribution to breast cancer risk because many are carcinogenic and because they can impair reproductive capacity of wildlife. In laboratory tests, many environmental contaminants have been found to act like reproductive hormones. Therefore, one mechanism by which chemical exposures may conspire to contribute to cancer is by mimicking hormones. Both women and men may be affected by these exposures. Hormones are also thought to play a role in prostate cancer, ovarian cancer, uterine cancer, testicular cancer, and colon cancer. Indeed, hormonal disruption may be associated with a broad range of biological effects: reproductive dysfunction, neurological problems, and immunological difficulties.

More and more evidence exists about the hormonal action of environmental contaminants. DDT and DES can hasten the onset of puberty in animals. On the other hand, TCDD (dioxin) can delay it. In women, early puberty is a risk factor for breast cancer. These effects are also related biologically to gender modification in turtles and alligators, with which we are all familiar.[4 5] Another hormonal effect of DDT has been found by Walter Rogan and his colleagues at NIEHS.

In two studies, they found that women in the U.S. and in Mexico who had high levels of DDE also breastfed for shorter periods.[6 7] Recently we have learned that DDT can act as an anti-androgen in the rat, counteracting male hormones and interfering with reproductive development.[8] Another pesticide, vinclozolin, has been found in animal tests to have pro-androgenic effects.[9] Androgens regulate male development, fertility and possibly male reproductive cancer. Chemicals of this kind may add to the body's hormone burden or they may affect the hormonal balance, as in the level of estrogen relative to that of androgen (i.e. testosterone).

In addition to hormone disruption, a number of chemicals are known to act through other routes in animals to cause breast cancer (e.g. perchloroethylene, polycyclic aromatic hydrocarbons), although links to breast cancer in women are only now beginning to emerge. Most chemical exposures in this category are difficult to measure in humans, especially long after exposure occurs. But there are some important recent findings. Of special note is the report from investigators at the New York State Department of Health who used a unique geographic method to assess exposure according to street address. They found elevated risk of breast cancer on Long Island associated with residence near potentially hazardous chemical facili-

ties.[10] Investigators at the National Cancer Institute also reported breast cancer rates elevated among occupation with a number of chemical exposures.[11] These are early leads that will be followed up by investigations that attempt to more precisely measure exposure to environmental agents in relation to risk.

Exposure to environmental chemicals must be considered as possible preventable risk factors for breast cancer and other hormonally related diseases. This is especially true for breast cancer, because it affects so many women and their families, and because we have not been able to identify other means of preventing this devastating disease. We know that environment is important, but the exact reasons have eluded definition. We have banned many chemicals which fit into this category, especially those that are biologically persistent and carcinogenic in animals (DDT, chlordane, hexachlorobenzene, PCBs and PBBs). But their continuing presence in the environment makes it possible for us to detect them even now in American men and women. There are numerous other hormonally active chemicals now in commerce, including atrazine and methoxychlor, which are of concern. New chemicals should be evaluated for their hormonal potential, as Congressman Waxman has previously recommended.

Because so little is known about breast cancer causation, we cannot ignore the possibility that chemical exposures may play a role in this disease. Rates of breast cancer occurring in the U.S. have risen steadily since 1940. During that same period, levels of pesticide and PCB residues in human adipose tissue in the U.S. have shown parallel increases. We cannot now prevent breast cancer through known risk factors. But environmental exposures to harmful chemicals can be avoided, and therefore diseases associated with such chemicals may then be prevented. Therefore the efforts of this committee to protect health by preventing adverse environmental is of the greatest importance.

REFERENCES

[1] Falck FY, Ricci A, Jr, Wolff MS, Godbold J, Deckers J: Pesticides and polychlorinated biphenyl residues in human breast lipids and their relation to breast cancer. Arch Environ Health 47: 143-146, 1992.

[2] Wolff MS, Toniolo P, Lee E, Rivera M, Dubin N. Blood levels of organochlorine residues and risk of breast cancer. J Natl Cancer Inst 85; 648-652, 1993.

[3] Krieger N, Wolff MS, Hiatt RA, Rivera M, Vogelman J, Orentreich N. Breast cancer and serum organochlorines: a prospective study among white, black, and Asian women. JNCI 86: 589-599, 1994.

[4] Guillete LJ, Gross TS, Masson GR, Matter JM, Percival HF, Woodward AR. Developmental abnormalities of the gonad and abnormal sex hormone concentrations in juvenile alligators from contaminated and control lakes in Florida. Environ health persp 102: 680-688, 1994.

[5] Bergeron JM, Crews D, MeLachlan JA. PCBs as environmental estrogens: turtle sex determination as a biomarker of environmental contamination. Environ health persp 102: 780-781, 1994.

[6] Rogan WJ, Gladen BC, McKinney JD, Carreras N, Hardy P, Thullen J, Tingelstad J, Tully M. Polychlorinated biphenyls (PCBs) and dichlorodiphenyldichloroethane (DDE) in human milk: effects on growth, morbidity, and duration of lactation. Am j pub health 77: 1294-1297, 1987.

[7] Gladen BC, Rogan WJ. DDE and shortened duration of lactation in a northern Mexican town. Amer j publ health 85: 504-508, 1995.

[8] Kelce WR, Stone CR, Laws SC, Gray LE, Kemppainen JA, Wilson EM. Persistent DDT metabolite *p,p'*-DDE is a potent androgen receptor antagonist. Nature 375: 581-585, 1995.

[9] Kelce WR; Monosson E; Gamcsik MP; Laws SC; Gray LE Jr Environmental hormone disruptors: evidence that vinclozolin developmental toxicity is mediated by antiandrogenic metabolites. Toxicol-Appl-Pharmacol. 126: 276-85 1994.

[10] Melius JM, Lewis-Michl EL, Kallenbach LR, Ju CL, Talbot TO, ORR MF, Lauridsen PE. Residence near industries and high traffic areas and the risk of breast cancer on Long Island. Report from the NYS DOH, April 1994.

[11] Cantor KP, Stewart PA, Brinton LA, Dosemeci M. Occupational exposures and female breast carcinogenic mortality in the United States. JOEM 37: 336-348, 1995.

Mr. BILIRAKIS. Thank you very much, Doctor.

Mr. Hopkins for your opening statement, please, sir.

STATEMENT OF EDWARD HOPKINS

Mr. HOPKINS. Thank you, Mr. Chairman and members of the committee for the opportunity to testify here today. My name is Ed Hopkins. I am environmental director of Citizen Action, the Nation's largest consumer and environmental organization with 3 million members in 33 States.

In our view, the most important task before Congress as it addresses pesticide reform should be to ensure that pesticide tolerances protect infants and children and after a 5-year effort, we now have an excellent blueprint before us to do that. If Congress enacts H.R. 1627, however, we are concerned that it will make an already weak regulatory system even worse and I would like to focus on how, in addition to repealing the Delaney Clause, which has received most of the attention, the provisions of H.R. 1627 would actually weaken health standards in several other respects.

First, H.R. 1627 weakens current standards for pesticides in raw foods by requiring EPA to set tolerances based on benefits, economic benefits, to food producers. When granting a tolerance now under Section 408, EPA considers benefits to consumers of an adequate and wholesome and economical food supply. Under H.R. 1627, EPA would be required to consider the benefits of a pesticide's use to growers. EPA could establish a tolerance that would carry a risk to consumers which would be greater than negligible if it found that growers in a particular region needed that pesticide to produce a specific crop. The public would bear the health risks, the producers would reap the economic benefits.

The NAS report specifically criticized the practice of establishing tolerances which are not based principally on health considerations. In requiring the EPA to consider regional growers' ability to produce crops, H.R. 1627 takes policy in exactly the opposite direction from that recommended by the NAS report.

Second, H.R. 1627 weakens current standards for pesticides in processed food. Current Section 409 tolerances allow no consideration of benefits, simply requiring that food additives in question, such as concentrating pesticide residues, be safe. This has been interpreted in current case law to mean that there is a reasonable certainty of no harm. H.R. 1627 replaces this standard with a much weaker negligible risk, consumer risk and producer benefit standard that I just described.

Third, H.R. 1627 weakens current standards for noncarcinogens in food. Much of the legislative debate has been about carcinogens but children's exposure to noncarcinogens, particularly neurotoxins, received considerable attention in the NAS report. H.R. 1627 would weaken standards for these pesticides in food.

Current standards do no permit a negligible risk of birth defects from pesticides in food. They apply safety standards designed to prevent no birth defects at all. Similarly, the standards do not permit a negligible amount of brain and central nervous system toxicity; they are designed to prevent it from occurring at all.

H.R. 1627 would substantially weaken this. Rather than striving for no risk of these noncancer effects, regulators could allow higher risks of—higher levels of pesticides in food as long as the risks of human health damage were negligible, possibly diluted to provide economic benefits to regional producers again.

Because of these and other deficiencies, we strongly urge Congress not to enact H.R. 1627. But, if it does, it should at least mitigate the damage that that bill would cause and provide a minimum of consumer protection by passing H.R. 1771. This bill contains three elements of great importance to consumers. We think it provides a much more certain road toward carrying out the rec-

ommendations of the National Academy of Sciences report because it specifically directs EPA to do that.

Second, we also think it is a common sense policy not to permit cancer-causing chemicals in the food supply. But if Congress decides to allow these chemicals in food, it should at least require a notice when consumers are eating food that has been sprayed with known or probable human carcinogens. This notice serves two purposes. First, it gives consumers knowledge about the product and the choice of choosing an alternative. Second, it will give food producers an incentive not to use known or probable carcinogens.

If it is good public policy for people to have information on food's nutritional benefits, like fat or sodium or cholesterol, it seems equally reasonable for people to know about cancer-causing pesticides that were applied to the food.

Thank you, Mr. Chairman.

[The prepared statement of Edward Hopkins follows:]

PREPARED STATEMENT OF ED HOPKINS, ENVIRONMENTAL DIRECTOR, CITIZEN ACTION

Mr. Chairman, distinguished members of the subcommittee, thank you for the opportunity to testify today on pesticide and food safety legislation your committee is considering. I am Ed Hopkins, Environmental Director of Citizen Action, the nation's largest consumer and environmental organization with three million members in 33 states.

For years, evidence has been growing that current pesticide policies are broken and badly in need of repair.

- The 1993 National Academy of Sciences (NAS) study, *Pesticides in the Diets of Infants and Children,* concluded that the current pesticide tolerance system fails to protect children.
- More than 20 General Accounting Office reports over the last 15 years have critiqued EPA's and FDA's pesticide programs. In virtually every area, from delays in re-registration to inadequate monitoring and enforcement, these reports reinforce the impression that the existing regulatory system has not done a good job protecting consumers.
- Illegal pesticides on food are a routine occurrence, even after foods are washed, peeled and ready for consumption, as demonstrated by a recent Environmental Working Group analysis *(Forbidden Fruit: Illegal Pesticides in the U.S. Food Supply, 1995).* Inadequate enforcement tools leave the Food and Drug Administration ill-equipped to curb these violations by imposing effective sanctions.
- A complex regulatory structure combined with inadequate resources means that it routinely takes EPA many years to reach a conclusion about a pesticide once a serious public health problem has been raised. These lengthy delays do little to build consumer confidence in the government's ability to safeguard the food supply from pesticides.
- While some farmers have demonstrated convincingly that it is possible and even profitable to grow food using fewer chemical pesticides, most farmers have few incentives and scant governmental support for reducing their pesticide use.

The policies embodied in H.R. 1627 will solve none of these problems. If Congress enacts H.R. 1627, it will make an already inadequate pesticide regulatory system worse. A combination of fundamental policy changes would weaken current standards and allow more pesticides in the food supply, increasing risks of cancer, birth defects, and damage to the neurological and immune systems. Some of the most important changes include the following: substituting a vague "negligible" risk standard for the Delaney Clause and weakening the law's other health protection standards; shifting the burden of proof that pesticides meet current health and safety standards to EPA from the pesticide registrant; requiring EPA to dilute health-based standards by accounting for agricultural practices, a policy the National Academy of Sciences report on infants and children specifically criticized; making it virtually impossible for states to set health protection standards or even require warnings; and creating a strong presumption that food safety standards established under the CODEX should override U.S. pesticide tolerances.

H.R. 1627 Weakens Current Health Standards

I especially want to highlight the potential effects of some of the proposed legislative changes on children's health. Congress is in a strong position to enact legislation to protect the health of infants and children from pesticides, based on the five-year NAS report completed in 1993.

At first glance, this year's version of H.R. 1627 appears to be an improvement over the version introduced last session in that it requires the collection of data concerning food consumption of infants and children. It also contains a general requirement that the EPA develop and implement procedures that ensure that pesticide tolerances safeguard children's health.

In reality, however, the provisions in H.R. 1627 would actually weaken children's protections from pesticides in three respects (in addition to repealing the Delaney Clause), and in other ways prevent the EPA from carrying out the NAS recommendations if it tried to do so. Several provisions in the bill support this assertion:

H.R. 1627 weakens current standards for pesticides in raw foods by requiring EPA to set tolerances based on benefits to food producers. When granting a tolerance under Section 408, the regulatory system requires EPA to consider benefits to *consumers* of an adequate, wholesome and economical food supply. The nutritional and economic benefits to consumers of a wholesome, abundant food supply are weighed against the health risks which the use of pesticides pose to consumers.

Under H.R. 1627, EPA would be required to consider the benefits of a pesticide's use to growers. The EPA could establish a tolerance that would carry a risk to consumers which would be greater than "negligible" if it found that growers in a particular region needed that pesticide to produce a specific crop. So the benefits EPA would consider and use to justify a higher tolerance if H.R. 1627 were to become law are not benefits to consumers, but economic benefits to growers.

Here's how this could work: Under current law, a temporary $25 million loss to the citrus industry would be measured in terms of its effect on the availability and price of citrus products in the marketplace, not in terms of grower profits. This cost would be weighed against public health effects of the pesticide in question. An increase in the overall price of citrus of $25 million per year would cost the American public about 10 cents per person per year, not accounting for the ability of imported citrus to pick up the slack.

Under the current standard, in this scenario, pesticides that present a greater than negligible risk to the public are not likely to be allowed in food because the increased costs to consumers would hardly be noticeable. But if EPA is required to consider the economic benefits to the citrus growers, it could end up allowing use of a pesticide which it would otherwise not have permitted on health grounds. The public would bear the health risks; the producers would reap the economic benefits. That's why growers and the pesticide industry want the standard changed.

The NAS report specifically criticized the practice of establishing tolerances which are not based principally on health considerations. According to report:

> Tolerances constitute the only tool the EPA has under the law for controlling pesticide residues in food. *To ensure that infants and children are not exposed to unsafe levels of pesticide residues, the committee recommends that EPA modify its decision-making process for setting tolerances so that it is based more on health considerations than on agricultural practices.* (NAS, *Pesticides in the Diets of Infants and Children,* page 8. Emphasis in the original.)

In requiring the EPA to consider regional growers' ability to produce crops, H.R. 1627 takes policy in exactly the opposite direction from that recommended by the NAS report. Superimposing consideration of benefits to growers will further dilute the ability of tolerances to protect infants and children.

H.R. 1627 weakens current standards for pesticides in processed food. Current Section 409 tolerances allow no consideration of benefits, simply requiring that the food additive in question (in this case, concentrating pesticide residues in processed foods) be safe. This has been interpreted in case law to mean that there is a "reasonable certainty of no harm" from the addition of the additive to the food supply.

H.R. 1627 throws this standard out the window and replaces it with the much weaker risk/benefit standard described above.

H.R. 1627 weakens current standards for non-carcinogens in foods. Much of the legislative debate about pesticides has centered on the Delaney Clause and carcinogenic pesticides in food, but children's exposure to non-carcinogens, particularly neurotoxins, received considerable attention in the NAS report. H.R. 1627 would weaken standards for these pesticides in food.

For the several hundred pesticides that do not cause cancer in animal studies, the EPA sets standards that in theory provide absolute protection from these health ef-

counter in the supermarket. Conducted in late January 1995, the key findings of this poll were that 84 percent of Americans would be willing to pay an extra $2 per year per family member for groceries to reduce pesticide use. This would result in approximately $500 million in new funding to help farmers reduce their use of pesticides and fertilizers.

Ninety percent of Americans would be willing to pay at least an extra 50 cents per year per family member for groceries to reduce pesticide use. This is equivalent to $125 million in additional revenues.

It should come as no surprise that an overwhelming percentage of consumers are willing to pay slightly more at the checkout line if they could receive food grown with fewer pesticides. Years of polling by both industry and consumer groups alike show that consumers' views of pesticide residues have been consistent.

What is surprising is the extent to which the proposed legislation, H.R. 1627, is out of touch with this consumer viewpoint. The Food Quality Protection Act is legislation that is headed in the wrong direction. H.R. 1627 will likely increase the presence of toxic pesticide residues in the food supply. It ignores the fact that conventional testing protocols cannot always identify long-term health risk associated with pesticide use while studies can always be produced that show short-term economic loss, whether real or imagined.

H.R. 1627 puts the health of companies before the health of children. The bill weakens consumer protection standards throughout the Federal Food, Drug and Cosmetic Act sections addressing pesticide residues. In the name of improving safety, the legislation repeals needed consumer protections without filling any of the gaps in the existing statutes. For example, H.R. 1627 truly contains the exception that swallows the rule.

The bill adopts a negligible risk standard but then it provides a number of opportunities for overriding that standard. For example, the negligible risk standard can be avoided where "the availability of the pesticide would enable domestic growers to maintain the availability of an adequate, wholesome or economical food supply for consumers." This provision alone is so broad that it will likely permit unfettered use of hazardous chemicals and put the brakes on research and development of safer pesticides.

The bill also repeals the Delaney Clause, which represents the only truly public health based standard for pesticide tolerance setting.

Although CSPI would support a rigorous and conservative application of the negligible risk standard for cancer-causing chemicals, the standard must be coupled with needed new protections against other hazards. We believe that the following amendments would make H.R. 1627 less onerous and these are the amendments contained in H.R. 1771.

Congress should require the EPA to set tolerances at levels that protect children and, please, where we don't have perfect science, let's give the kids the benefit of the doubt.

Congress should prohibit the EPA from approvi ci tl
may cause cancer, including breast cancer, and t
of highly toxic chemicals.

able carcinogens, he or she will be able to make that choice. Currently, that information is unavailable to consumers.

Second, the pesticide right-to-know provision in H.R. 1771 will give food producers an incentive not to use known or probable carcinogens. This information-based, non-regulatory approach should put a premium on foods which have not been treated with these chemicals, stimulating the development of alternative pest management techniques and rewarding farmers through the marketplace.

If it's good public policy for consumers to have information on a food's nutritional benefits, it seems equally reasonable for people to know if cancer-causing pesticides were applied.

Prevention of Breast Cancer and other Reproductive Disorders

As the Subcommittee knows from hearings it held during the last session of Congress, recent scientific discoveries suggest that some pesticides mimic the action of the hormone estrogen and may increase the risk of breast cancer. One in nine women are at risk from breast cancer. These pesticides may also increase the risk of prostate and testicular cancer and males and reduce sperm counts.

While H.R. 1627 fails to specifically address this important problem, H.R. 1771 requires EPA to make a specific written finding as to whether a pesticide tolerance is "reasonably anticipated" to cause breast cancer or serious reproductive disorders. If a pesticide fails this test, then EPA may not prescribe a tolerance.

If Congress does not see fit to phase out this class of pesticides altogether, this provision in H.R. 1771 is a reasonable policy to impose to reduce public exposure to estrogenic chemicals.

In conclusion, we urge the Committee not to roll back consumer protections from pesticides on food. If Congress takes that step, we urge you to at least adopt the minimal consumer protection provisions embodied in H.R. 1771. Thank you again, Mr. Chairman, for the opportunity to testify.

Mr. BURR [presiding]. Thank you, Mr. Hopkins.

Ms. DeWaal.

STATEMENT OF CAROLINE SMITH DeWAAL

Ms. DEWAAL. Good afternoon. My name is Caroline Smith DeWaal. I am Director of Food Safety for the Center for Science in the Public Interest. We are supported by over 750,000 consumers who are particularly interested in nutrition and food safety issues.

Americans spend more than $17 billion a year on pesticides and chemical fertilizers to grow their cops and to control pests and weeds in homes, gardens and businesses. While pesticides and fertilizers help deliver an abundant and inexpensive food supply and control weeds and pests, the environmental and health problems caused by the use of pesticides alone are estimated to reach $8 billion per year. These chemicals affect water quality, food safety, farmworker safety and wildlife habitats. Production of pesticides and fertilizer use would minimize and in some cases eliminate these costs to society.

Consumers' concerns about pesticide use are well documented. Year after year, opinion polls tell us that consumers don't like chemical residues in their food. Since 1989, the Food Marketing Institute which is made up of food retailers and wholesalers, conducts a trend survey every year and consumers have consistently told them that they rank pesticide residues as one of their top food safety concerns. In their latest survey that was released just this month, nearly 3 out of 4 of the respondents ranked pesticide residues in food as a serious hazard.

In a national opinion poll conducted for the Center for Science in the Public Interest last January, consumers showed strong support for funding farming methods that reduced pesticide use overall, even if it meant that they had to pay more at the checkout

counter in the supermarket. Conducted in late January 1995, the key findings of this poll were that 84 percent of Americans would be willing to pay an extra $2 per year per family member for groceries to reduce pesticide use. This would result in approximately $500 million in new funding to help farmers reduce their use of pesticides and fertilizers.

Ninety percent of Americans would be willing to pay at least an extra 50 cents per year per family member for groceries to reduce pesticide use. This is equivalent to $125 million in additional revenues.

It should come as no surprise that an overwhelming percentage of consumers are willing to pay slightly more at the checkout line if they could receive food grown with fewer pesticides. Years of polling by both industry and consumer groups alike show that consumers' views of pesticide residues have been consistent.

What is surprising is the extent to which the proposed legislation, H.R. 1627, is out of touch with this consumer viewpoint. The Food Quality Protection Act is legislation that is headed in the wrong direction. H.R. 1627 will likely increase the presence of toxic pesticide residues in the food supply. It ignores the fact that conventional testing protocols cannot always identify long-term health risk associated with pesticide use while studies can always be produced that show short-term economic loss, whether real or imagined.

H.R. 1627 puts the health of companies before the health of children. The bill weakens consumer protection standards throughout the Federal Food, Drug and Cosmetic Act sections addressing pesticide residues. In the name of improving safety, the legislation repeals needed consumer protections without filling any of the gaps in the existing statutes. For example, H.R. 1627 truly contains the exception that swallows the rule.

The bill adopts a negligible risk standard but then it provides a number of opportunities for overriding that standard. For example, the negligible risk standard can be avoided where "the availability of the pesticide would enable domestic growers to maintain the availability of an adequate, wholesome or economical food supply for consumers." This provision alone is so broad that it will likely permit unfettered use of hazardous chemicals and put the brakes on research and development of safer pesticides.

The bill also repeals the Delaney Clause, which represents the only truly public health based standard for pesticide tolerance setting.

Although CSPI would support a rigorous and conservative application of the negligible risk standard for cancer-causing chemicals, the standard must be coupled with needed new protections against other hazards. We believe that the following amendments would make H.R. 1627 less onerous and these are the amendments contained in H.R. 1771.

Congress should require the EPA to set tolerances at levels that protect children and, please, where we don't have perfect science, let's give the kids the benefit of the doubt.

Congress should prohibit the EPA from approving pesticides that may cause cancer, including breast cancer, and phaseout the use of highly toxic chemicals.

Congress should also mandate the labeling of crops containing possible carcinogenic residues. This will give consumers the freedom of choice at the supermarket.

In closing, CSPI urges this committee to reject H.R. 1627 unless it is substantially revised. The annual costs of pesticide use are enormous and consumers have repeatedly expressed their preference that fewer chemicals be used to grow their food. Yet this legislation is headed down the road toward unfettered pesticide use. Increasing the use of pesticides coupled with fewer consumer safeguards like the Delaney Clause will undoubtedly prove even more costly in the long run.

Thank you.

[The prepared statement of Caroline Smith DeWaal follows:]

PREPARED STATEMENT OF CAROLINE SMITH DEWAAL, DIRECTOR, FOOD SAFETY PROGRAM, CENTER FOR SCIENCE IN THE PUBLIC INTEREST

INTRODUCTION

American farmers, homeowners, municipalities and others spend more than $17 billion a year on pesticides and chemical fertilizers to grow their crops, and control pests and weeds in homes, gardens and businesses. While pesticides and fertilizers help deliver an abundant and inexpensive food supply and control weeds and pests, the environmental and health problems caused by the use of pesticides alone are estimated to reach $8 billion per year. These chemicals impact water quality, food safety, farm worker safety, and wildlife habitats. Reduction of pesticide and fertilizer use would minimize and, in some instances, eliminate these costs to society.

Consumers' concerns about pesticide use are well documented. Year after year, opinion polls tell us that consumers don't like chemical residues in their food and the risk these residues pose to their health and their families. Consumers view these risks as involuntary, as it is often difficult or expensive for consumers to avoid chemicals added to the food supply. Since 1989, in the Food Marketing Institute *Trends* Survey, consumers have consistently ranked pesticide residues as one of their top food safety concerns.[1] In their latest survey, released just this month, nearly three out of four respondents ranked pesticide residues in food as a "serious hazard."

In a national opinion poll conducted for the Center for Science in the Public Interest (CSPI) last January, consumers showed strong support for funding farming methods that reduced pesticide use overall, even if this meant they had to pay a little more money at the supermarket checkout line. Conducted over two days in late January 1995, the key findings of the poll were:

- 76 percent of Americans support levying a small charge on agricultural use is of pesticides as a way of funding sustainable agriculture.
- 86 percent of Americans think federal and state agriculture agencies should teach farmers how to use fewer pesticides.

Even if pesticide and fertilizer taxes resulted in increased food costs to consumers the poll demonstrated strong support:

- 84 percent of Americans would be willing to pay an extra $2 per year per family member for groceries to reduce pesticide use. This would result in $500 million that could be used to help farmers and others reduce their use of pesticides and fertilizers.
- 90 percent of Americans would be willing to pay at least an extra $.50 per year per family member for groceries to reduce pesticide use; this is equivalent to $125 million in additional revenue.

Why are consumers so motivated to get pesticides out of their food that they would pay more for the food itself? Four decades of carte-blanche use of pesticides and fertilizers has taken a serious toll on farmers' health, water quality, food safety, and fish and wildlife habitat in the United States.

The potential "side effects" of heavy chemical use for both agricultural and non-agricultural uses were not adequately recognized from the onset. Although several scientists raised questions about the potential harm posed by unfettered use of pes-

[1] Food Marketing Institute, *Trends in the United States: Consumer Attitudes and the Supermarket*, 1995.

ticides, their concerns were often dismissed as "hysterical" reactions to the new wave of technology symbolized by Dupont's corporate slogan—"Better Living Through Chemistry."

Only in the past 20 years have researchers begun to identify and quantify the damage caused by the extensive use of pesticides and fertilizers. These estimates are ongoing, and in some cases the full extent of the damage will not be known for years. What is clear, however, is that this national problem is enormous, multi-faceted, and will require substantial changes in farming practices and consumer habits to effectively reduce future damage.

HEADED THE WRONG DIRECTION: CONGRESS AND PESTICIDE REFORM

It should come as no surprise that an overwhelming percentage of consumers are willing to pay slightly more at the checkout line if they could receive food grown using fewer pesticides. And years of polling by industry and consumer groups alike show that consumers' views on pesticide residues have been consistent. What is surprising is the extent to which the proposed legislation, HR 1627, is out-of-touch with this consumer viewpoint.

The Food Quality Protection Act, HR 1627, is legislation that is headed the wrong direction. HR 1627 will likely increase the presence of toxic pesticide residues in the food supply. It ignores the fact that conventional testing protocols cannot always identify long-term health risks associated with pesticide use, while studies can always be produced to show short-term economic loss, whether real or imagined. HR 1627 puts the health of corporations before the health of children.

While there is strong support for basing pesticide tolerances on the best science available, there are inevitable gaps in the scientific basis for regulating these chemicals, particularly with respect to long term human health effects. Where these gaps exist, the benefit of the doubt should be in favor of protecting public health rather than protecting industry profits. But this is not the approach adopted in HR 1627.

The bill weakens consumer protection standards throughout the Federal Food, Drug and Cosmetic Act's sections addressing pesticide residues in food. In the name of improving safety, the legislation repeals needed consumer protections without filling any of the gaps in the existing statutes. For example, the new definition of pesticide chemicals contained in the legislation restricts regulation to active pesticide ingredients. This language will make it more difficult for the Environmental Protection Agency (EPA) to regulate the so-called inert ingredients that are toxic, such as asbestos fibers, benzene, formaldehyde, and vinyl chloride. Toxic inert ingredients can be found in much greater concentrations than the active ingredients in pesticides, and may represent a significant contributor to dietary exposure to toxic chemicals.[2] New language in the bill would limit the EPAs oversight over these chemical agents, and could result in increased dietary exposure to the most toxic inert ingredients in pesticides.

HR 1627 truly contains the exception that swallows the rule. The bill adopts a "negligible risk" standard, but then it provides a number of opportunities for overriding this standard. For example, the "negligible risk" standard can be avoided where "the availability of the pesticide would enable domestic growers to maintain the availability of an adequate, wholesome or economical food supply for consumers." This provision alone is so broad that it will likely permit unfettered use of hazardous chemicals and put the brakes on research and development of safer pesticides.

Even when the agency does apply the "negligible risk" standard, HR 1627 goes a step beyond what is generally considered appropriate from a public health standpoint by applying "negligible-risk" standard to all types of hazards associated with pesticide use, not just to cancer-causing chemicals. As generally understood, the "negligible risk" standard would allow adverse effects to occur at a frequency of one in one million cases.

Thus, instead of requiring the EPA to determine the threshold level of a chemical residue that is likely to cause birth defects or neurotoxic effects and setting a standard that is sufficiently below that threshold to assure the protection of the public, the legislation would allow for these adverse effects in a small number of cases. HR 1627 will put the government in the business of setting the permissible number of birth defects or neurotoxic effects that would be allowed from legal use of pesticides, thus condemning individuals and families to lifetime disability and costs.

The bill also repeals the Delaney clause, which bans the concentration of cancer-causing pesticides in processed foods. The Delaney clause represents the only truly

[2] National Research Council, *Pesticides in the Diets of Infants and Children*, National Academy Press, 1993.

public health-based standard for pesticide tolerance setting. Although CSPI could support a rigorous and conservative application of the "negligible risk" standard for cancer-causing chemicals as a substitute for the Delaney ban, the standard must be coupled with needed new protections against other hazards, such as reproductive and developmental effects, neurotoxic effects; and additional protections for children from all chemical hazards. In addition, pesticide reform legislation should move toward phasing out the most toxic pesticide chemicals, including those currently regulated under the Delaney clause.

HR 1627 ignores critical public health gaps in the present system that have been identified by the National Academy of Sciences and others:

- HR 1627 fails to mandate the implementation of any additional protections for children that were recommended by the National Academy of Sciences' report, *Pesticides in the Diets of Infants and Children.*
- HR 1627 fails to address the problems of multiple routes of pesticide exposure, such as from food, water, garden and home applications.
- HR 1627 fails to address the fact that our diet, indeed many individual foods, actually contain multiple pesticide residues; nor does it make any provision for examining toxicity resulting from interaction between different chemical agents.

The bill also does nothing to promote alternatives to agrichemical use. Pesticide use reduction techniques would clearly decrease the health and environmental costs discussed above, but they won't be adopted until farmers are assured that the techniques will work. Research and development is needed to assure that these techniques are effective in reducing pesticide use without harming farming productivity. We believe that farmers want to reduce the amount of chemicals they use to grow our food, both for food safety reasons and because these chemicals effect their own health. They need some training, however, in how to do it successfully.

Although the Center for Science in the Public Interest opposes HR 1627, we believe that the following amendments would make the bill less onerous:

1. Congress should require the EPA to set tolerances at levels that protect children.

The National Academy of Sciences' (NAS) 1993 report on pesticide tolerances and children documented that tolerance setting practices do not adequately protect children from the harmful effects of pesticide residues. The NAS made a series of recommendations to correct this deficiency. We support an amendment that would mandate implementation of the NAS recommendations to better protect our children from harmful effects of pesticide residues. Where we don't have perfect science, let's give kids the benefit of the doubt.

2. Congress should prohibit the EPA from approving pesticides that may cause cancer.

Cancer continues to be a leading cause of death, and many studies have documented the links between the use of pesticides and increases in cancers.[3] One form of cancer, breast cancer, has become a growing problem for American women. Since 1960, the risk of breast cancer more than doubled, from one in twenty to one in nine. Only about 30% of the victims have known risk factors, such as a late first pregnancy, limited breast-feeding, or a family history of the condition.[4] Many scientists attribute the increase in these cancers in part to the more frequent use of very potent chemicals which mimic the hormone estrogen in the body. These chemicals are sometimes found in pesticides. Some, like DDT, have already been banned. The EPA should be given a mandate to assure that, where chemicals are found to be a contributing factor to the development of breast or other cancers, these chemicals should never reach the market.

3. Congress should mandate the labeling of crops containing possible carcinogen residues.

In opinion poll after opinion poll, consumers express concerns about pesticides in their food. Part of this concern clearly arises from the fact that consumers aren't informed about the chemicals that are used. They aren't given the information that would allow them to select food with low risk pesticides over those containing more toxic ones.

With the more permissive use of cancer-causing chemicals authorized by HR 1627, consumer confidence in the safety of fruits and vegetables will only be weakened. Given the tremendous nutritional benefits of fruits and vegetables, Congress should

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[3] For a review of some of these studies, see *Funding Safer Farming: Taxing Pesticides and Fertilizers*, Center for Science in the Public Interest, May 1995, pp. 9, 13.

[4] "Environmental Estrogens Linked to Reproductive Abnormalities, Cancer," *Chemical and Engineering News*, January 31, 1994.

act to eliminate the distrust that lack of information about chemical inputs creates. Food that is treated with cancer-causing pesticides should be clearly labeled to permit greater consumer choice in the market.

In closing, CSPI urges this committee to reject HR 1627. As our recent report, *Funding Safer farming*, clearly documents, the annual costs of pesticide use are enormous. Consumers recognize these costs, and have repeatedly expressed their preference that fewer chemicals be used to grow their food. Yet, this legislation is headed dewn the road toward unfettered pesticide use. Increasing the use of pesticides, coupled with fewer consumer safeguards, will undoubtedly prove even more costly in the long run.

Mr. BURR. Thank you, Ms. DeWaal and thank you to the rest of our witnesses who are here to testify today and for the committee, if it hadn't been known, we had a late night last night. If we look a little bleary-eyed up here, and many have multiple hearings today so if you hear us talk about Clean Air, we are just—we have got the wrong panel in mind, but bear with us.

I am also told that we have about 40 minutes before we can expect the next vote so we will do everything we can to make sure that we move through it as quickly as we can to cherish your time and we appreciate you being here.

At this time I would like to turn the questioning over to the ranking minority member, Mr. Waxman.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I want to thank this panel for your excellent testimony and particularly Mr. and Mrs. Chuda and Mr. Eichler for traveling a long distance to be with us today.

One of my greatest concerns is to ensure that whatever pesticide legislation we do enact be based on the best possible science. I know this is a concern shared by many members of this subcommittee because many of my colleagues have emphasized the importance of sound science in talking about pesticide or any other environmental legislation.

Dr. Landrigan, you were the Chair of the National Academy of Sciences panel that examined the risks of pesticides to children. The NAS issued a comprehensive report in 1993 with important recommendations about how to improve regulation of pesticides.

Can you tell us whether H.R. 1627 is consistent with the recommendations of the National Academy of Sciences?

Mr. LANDRIGAN. Sir, H.R. 1627 is consistent with a few of our recommendations. I mentioned in my verbal testimony the provisions for increased surveillance are good, but in my opinion it falls short when it comes to the main recommendation.

The central recommendation of our report from the National Academy of Sciences was that tolerances for pesticide residues in foods must be set at levels that are low enough to protect children from disease—unequivocal in the way we expressed that—and my concern is that the provisions of H.R. 1627 will enable children to be exposed to levels of pesticide residues in foods that will increase risk of disease, that will increase risk of cancer, reproductive dysfunction, possibly of immune dysfunction and possible of future neurologic dysfunction and this is something that I just don't think that we should tolerate, sir.

Mr. WAXMAN. The bill, H.R. 1627, does not have that provision. I introduced a separate bill, and Section 3 of that bill would require EPA to determine whether pesticides are reasonably anticipated to harm children before issuing a tolerance which would allow them

to be used. It also says that in making this determination EPA must implement the recommendations of the National Academy of Sciences.

Is this provision the kind of improvement in our pesticide laws that the NAS recommended?

Mr. LANDRIGAN. Yes, sir, exactly, and I commend you for having written that in H.R. 1771.

Mr. WAXMAN. Dr. Reigart, you have emphasized the importance of health-based standards for regulating pesticide exposure in food. H.R. 1627 does not appear to have a health-based standard because it expressly allows a greater than negligible risk if EPA determines that such greater risk is outweighed by economic benefits to growers. This is a cost benefit standard, not a health standard.

Does the National Academy of Pediatrics support or oppose the approach of H.R. 1627?

Mr. REIGART. This approach clearly does not meet our criteria. As I said in my prepared testimony, the principle of "first, do no harm," that is, first show that a pesticide is safe for children before looking at the potential benefit from it, is the basic medical approach and has been supported throughout by the Academy of Pediatrics.

H.R. 1627 actually has an enormous loophole in allowing greater than negligible risk under very broad terms and this is clearly not consistent with the desires of the Academy of Pediatrics.

Mr. WAXMAN. In contrast, our bill, H.R. 1771, would have a standard that would say that pesticides be reasonably anticipated not to harm children, and it would prevent the issuance of a tolerance expected to have this effect.

Does the National Academy of Pediatrics endorse H.R. 1771?

Mr. REIGART. Well, actually the Academy would probably like you to go a little further in requiring that they be demonstrated to be safe for children rather than a reasonable expectation of no harm, but certainly it is a lot closer to our desires than H.R. 1627.

Mr. WAXMAN. At the least, we ought to say that we shouldn't allow——

Mr. REIGART. At the very least——

Mr. WAXMAN. [continuing] pesticide where we have a reasonable anticipation that it is going to harm kids?

Mr. REIGART. That's correct.

Mr. WAXMAN. Okay.

Mr. REIGART. As I said, it goes a long ways but it isn't even as far as we would probably prefer.

Mr. WAXMAN. Dr. Wolff, I want to switch from discussing children to discussing breast cancer and reproductive disorders.

Are there sound scientific reasons for being concerned that pesticide exposure may increase risk of breast cancer and reproductive disorders?

Ms. WOLFF. There seems to be more and more evidence in the direction.

Mr. WAXMAN. And you have told us that there is evidence that—that there is a causal relationship. In light of this evidence does it make sense to adopt a provision like Section 4 in H.R. 1771 which requires EPA to assess the likelihood that pesticide exposure will contribute to breast cancer and reproductive disorders?

WOLFF. I think it is incumbent upon us to do that.
WAXMAN. Thank you very much. Thank you, Mr. Chairman.
BURR. I thank the gentleman. The Chair would recognize Dr.
n.
COBURN. Thank you, Mr. Chairman, and I thank each of you
ing here.
a Member of Congress and also as a physician, one of our
st difficulties is to match science with reasoned thought and
l what we see from the scientific community versus what we
)m the broader picture as well.
I listened to the testimony I just had a few questions that
f all I would like to ask of the physicians on the panel, if I
, and then maybe move from there.
Wolff, you mention the association of certain pesticides with
sed incidence, potentially an increased incidence, of breast
: possibly through its offsetting or anti-androgen effects, but
ere in fact other studies that show that there is not a correla-
or example like DDT?
WOLFF. I'm not a physician, but can I answer that question
ıy?
COBURN. Yes, you can.
WOLFF. I think you are referring to the most recent study
vas published that did not in a statistically significant sense
rt or confirm the earlier findings.
re are a lot of research investigations underway now that I
will help us understand that a little bit better and, strictly
ing, that certainly is so——
COBURN. Is there a particular reason why you didn't mention
study in your testimony, that you referenced studies that
d that position but didn't reference——
WOLFF. I think I did mention—I think I mentioned them all.
COBURN. You mentioned the study in "Public Health and Ep-
)logy Reports of Ontario," August 25, 1994? Is that referenced
ır testimony?
WOLFF. In my testimony I mentioned the three studies that
onally have been involved in, one of which did not show sta-
ılly significant confirmation of the earlier two studies that I
nvolved in. A number of other people in the scientific lit-
re have said that they felt that that study actually was very
rtive of the earlier findings even though it didn't meet statis-
ıignificance.
hat the one you were talking about?
COBURN. Yes.
WOLFF. Perhaps there is another that——
COBURN. Well, I am referring to one from "Public Health and
miology Reports of Ontario," Volume 5, Number 8, August 26,
which talks about no correlation between DDT and breast
r.
WOLFF. This is a scientific study——
COBURN. Yes, it is.
WOLFF. [continuing] or it's a review? Perhaps it's a review
earlier studies.
COBURN. Well, actually I'll be happy to visit with you after
—

Ms. WOLFF. Okay, okay——

Mr. COBURN. I have not read the entire study, just the summary.

Doctors, do we in fact have prospective studies to tell us what risk levels should be on children? I'm talking prospective studies, scientific studies that say this is the level at which there is no risk?

Mr. LANDRIGAN. Let me answer it this way, if I may, Mr. Congressman.

We undertook in our analysis a very careful and thorough review—it took us 5 years to accomplish it—of how EPA and the other regulatory agencies evaluate the toxicity of pesticides.

A major finding of our report is that there is a pervasive lack of adequate testing data for pesticides that are used in the marketplace and in particular, sir, there is a lack of data on the toxic effects of pesticides—when young organisms, young animals or young children, are exposed to pesticides there's virtually no data on the long-term consequences of early exposure.

Mr. COBURN. I understand that, but that is why I asked the question are there——

Mr. LANDRIGAN. We're flying blind.

Mr. COBURN. [continuing] there prospective studies ongoing today that will help us answer these questions?

Mr. LANDRIGAN. There are some——

Mr. COBURN. Should we repeat asbestos all over again in this country and the costs associated with that, going on the false supposition that we had a marked increase in risk when in fact the science now shows that we increased the risk by doing what we did on asbestos?

What I want to do is trust your medical opinion but I want to find out are we doing the science to make the decisions? Are the scientific studies being done on pesticides right now prospectively on exposure to children by weight and body through time that we are going to find out the answer to these questions, or are we just going to ban the pesticides and say they might?

Mr. LANDRIGAN. Well, the asbestos was an absolute disaster. I am from Mount Sinai Medical Center and my predecessor at Mount Sinai was Professor Irving Selikoff, who was the man who established the link between asbestos and cancer and by the time the asbestos epidemic plays out in this country 25 years from now into the next century, there will have been over 300,000 deaths from asbestos. We most certainly do not wish to repeat that tragedy.

Mr. COBURN. And we will have increased significantly the number of people that are going to die from it by removing it.

Mr. LANDRIGAN. Well, that's a whole other debate.

Mr. COBURN. I'll be happy to debate that one with you, too, but let's stay with this.

Mr. LANDRIGAN. Okay. Well, in the case of pesticides, the basic situation that we are in is that most of the pesticides to which our children are being exposed have not been adequately tested. This is a national scandal and we said that in the report from the National Academy.

Mr. COBURN. But I still haven't gotten an answer from you.

Are there ongoing prospective studies for these pesticides?

Mr. LANDRIGAN. For the most part not, sir.

Mr. COBURN. Okay. That is the question—so the science is not there now and there is no plan to get the science?

Mr. LANDRIGAN. Well, I can't speak for the EPA but it is my understanding that they are improving their tests, but at the present time we are letting pesticides on the market, inadequately tested, and we are hoping that they don't cause damage to kids, but we are not testing them. We are failing in our primary responsibility as physicians to do no harm.

Mr. COBURN. Thank you.

Mr. BURR. The gentleman's time has expired and we will try to go back through for another series of questions for those who have additional questions.

The Chair would recognize Mr. Stupak.

Mr. STUPAK. Thank you, Dr. Landrigan.

I am looking at page 7 of your testimony and you said, correct me if I am wrong, where it is underlined on Delaney Clause, you would be willing to replace the Delaney Clause if it were replaced by language directing the Federal agencies to employ state-of-the-art science to prove clear protection for America's children against toxic pesticides.

Mr. LANDRIGAN. Yes, sir.

Mr. STUPAK. Could you elaborate on that a little bit more, what you would like to see, if Delaney was repealed on that?

Mr. LANDRIGAN. Well, back to first principles. The first thing I would like to see is children protected from unnecessary exposure to toxic pesticides and I would like to see them protected from the disease that I deeply fear will result from that exposure. That is the goal.

So then it becomes a question of ways and means.

As far as Delaney is concerned, Delaney is not perfect. A lot of people don't like Delaney because it draws a bright line, it is black-and-white, it allows no wiggle room, it allows no discretion. And some of my colleagues in the risk assessment community have argued that Delaney ought to be replaced by something that allows consideration of different pesticides. We know that all pesticides are not equal, we know that some are more toxic than others and some would like to see Delaney removed and replaced by something that would allow the regulatory agencies to take cognizance of those differences, all well and good.

The problem with the proposal that is made in H.R. 1627 is that it would quietly do away with Delaney and replace it with a rule of law which is so loose, which has been so elegantly described by Ms. DeWaal, that it would allow, probably, increased use of toxic pesticides and further erosion of the protections that currently exist under Delaney. Delaney is not all bad; it has done a good job for nearly 4 decades. We should not discard it lightly.

Mr. STUPAK. Whatever language is agreed upon, whether it is retaining Delaney or language to provide the state of our science, should also include adults, too, right? I mean, the purpose here is not just children, you know, as has been the emphasis here today but also to adults also. But there would be different models or different standards you would use for adults as opposed to children, correct?

Mr. LANDRIGAN. That is correct. I think the emphasis on children is well placed, though, for the simple reason that children, in most cases, are the most vulnerable members of our society and so if we are able to write legislation and regulation that protects children, then per force we will protect everyone else.

Mr. STUPAK. Okay, but I am going back to Ms. Chuda's testimony then. How do we protect those type of situations if our emphasis is on children? You see the area I am having trouble with there?

How do we provide protection—I wouldn't want the language—the proposed language is to deal with children but how do we protect women in child-bearing years or how do we do that? We would have to have a different model to do that, right?

Mr. LANDRIGAN. There is some good language in the Clean Air Act. The Clean Air Act talks about setting standards such that they protect the most vulnerable members of our society and I think that maybe that is the blanket rule that you are reaching for.

Mr. STUPAK. Thank you. I have no further questions.

Mr. BURR. The gentleman's time has expired.

The Chair would recognize Dr. Ganske.

Mr. GANSKE. Thank you.

I want to express my sympathy to the Chudas for the tragedy that they have gone through. I have treated children with Wilm's tumor and in dealing with the death of a child, there is just no adequate answer. And I appreciate your being here.

Part of the difficulty of being a legislator is that you are torn by testimony such as yours and it elicits a great deal of sympathy from all of us, believe me. And yet, when we get into the realm of legislation, I think that in addition to sympathy, what we need is wisdom in deciding how to handle some of these problems because what may be sympathetic on an individual basis may not be wise overall and what may be sympathetic to one group may not be sympathetic to another group that is affected and so that is why these are difficult things.

I guess I would like to say that I think there is obviously no doubt that chemicals can cause cancer. I mean, all you have to do is open the sports page and look at what has happened with Mickey Mantle and the ingestion of ethanol or I remember from medical school reading epidemiologic studies about how people in southeast Asia inject or eat large quantities of pickled foods and get esophageal cancer from that and it was just the other night that I was eating a big steak that had a large amount of charring on the outside and I must admit the thought went through my mind, gee, I wonder if I am setting myself up with this barbecued steak for stomach cancer.

So clearly, you know, there are things to worry about but I guess we have to do something with common sense here too because, you know, would we recommend on the basis of those three examples that we never drink liquor, that we never eat a pickle, that we never barbecue? And the answer, of course, is no because there has to be some balancing in there and the other part of the reason is that there is definitely something related to dose relationships to risk.

And so I guess that brings me around to a question for Dr. Reigart and this gets, you know, down to I think really the Delaney Clause and I do have some problems with that. I mean, I think, Dr. Reigart, you probably acknowledged that one of the biggest problems we are having with children these days is increasing—and adults are increasing risks of melanoma related to sun exposure; is that correct?

Mr. REIGART. Certainly that is true, yes.

Mr. GANSKE. And so what do we do? All of us we recommend that we apply a lot of sun screen to our children early so that they can avoid the two or three or four episodes of bad sun burn that probably—early in life that predispose them to later melanoma, right?

Mr. REIGART. And we recommend keeping them out of the sun to protect them from exposure.

Mr. GANSKE. And at the same time though we recognize that playing outside is healthy, that getting some sun exposure is probably useful in terms of vitamin D and we certainly want them to grow up strong, healthy bodies, the whole thing, right?

Mr. REIGART. Yes, sir.

Mr. GANSKE. So we are applying some common sense to this, otherwise what we would do is we would keep our children inside all of the time and keep them totally covered up; is that right?

Mr. REIGART. That is correct.

Mr. GANSKE. If we were dealing with only—a zero risk goal. Would you agree with that?

Mr. REIGART. Yes.

Mr. GANSKE. It seems to me that there is some consensus on the panel that we need to move in some direction away from a zero risk assessment.

Mr. REIGART. I probably could sidestep the length of the question by saying the Academy has supported a true negligible risk standard to replace the Delaney Clause and I have testified to that effect in the last Congress. But it needs to be a true health-based negligible risk without exceptions.

Mr. GANSKE. And I appreciate everybody's testimony today because we are going to try to—we are looking at that.

I would like to point out in the limited amount of time that I have here that I do think that the EPA, as much as they are maligned sometimes, has been trying to, has been factoring in childhood testing because when they look at exposures to toxicity and calculate that over lifetimes, they are starting with childhood and going all the way through and then calculating a risk in parts per million over a 70-year life span; is that not correct?

Mr. REIGART. They have done a limited amount of those kinds of calculations, yes, sir. But according to both our assessment and the NAS panel, it is insufficient testing.

Mr. GANSKE. And I would also certainly agree that it would be useful to, with Dr. Coburn, that it would be useful to have better prospective studies in these areas and I am sure that you would agree with that also.

Thank you.

Mr. BURR. The gentleman's time has expired.

The Chair would take the opportunity to ask just a few questions and, again, to try to stay on schedule.

Mr. Eichler, let me say that in your testimony you expressed concern over the use of sulfur dioxide in Turkish apricots. You indicated that, based on your concern, you did some research which is admittedly more than I would probably do and most consumers, quite honestly. And you found that sulfur was an ingredient in gun powder, rubber vulcanization and insecticides. You are 100 percent correct because I did my research after reading your statement.

You are also correct that some products that contain sulfur and sulfur compounds are dangerous and even fatal. However, you seem unclear that sulfur and sulfur dioxide are two very different substances, as different as carbon, such as pencil lead, and carbon dioxide, which is found in forms of dry ice.

Understanding the potential dangers of sulfur as well as the differences between elements and their compounds, I was just curious to know if you were familiar with a product called Bactrum DS. Are you, sir?

Mr. EICHLER. No, I am not.

Mr. BURR. This is a common antibiotic, often used in the treatment of urinary tract infections, but it is often very frequently used for the treatment of acute otitis media, commonly known as a childhood ear infection. Bactrum DS is a sulfur-based antibiotic that is readily available as a pediatric suspension at local drug stores.

I guess my point is that the average consumer, and I would certainly include myself in that category, is not knowledgeable enough about chemistry and the periodic tables of elements to draw reasonable conclusions based upon labels such as the one that you describe from this experience possibly existing. It is and should be the responsibility, I believe, of scientists such as the ones at EPA, USDA and the NAS to determine which foods are safe for human consumption, and to disallow marketing of those which do not meet the appropriate standards. And, if you would, can you comment on that for me?

Mr. EICHLER. Okay. Well, first off, you know, as I have said in my statement, I don't come here as an expert in any form or way and all I know is what my short readings told me. Basically, I think you do underestimate a bit, you know, the American consumer. I think we do have at least some knowledge and, if nothing else, the point I was drawing here was the matter of choice. The thing is that if I see this, if I see some pesticide that is on there, I have the choice of, selecting that food or not. And I think that we certainly all would acquire enough knowledge about certain pesticides that that choice may be that we don't want to purchase that or not.

Mr. BURR. Even if that labeling misled the consumer about the risk or possibility of risk?

Mr. EICHLER. Well, you know, it is hard to say what kind of labeling would mislead you. Obviously, if you went into the store today, I am sure that sometime ago when maybe the difference between ground beef and hamburger and ground sirloin might mislead you. Possibly we could just label them all as ground beef because that is what they actually are.

Mr. BURR. In fact, don't we have agencies that are set up to take unsafe products off the shelves?

Mr. EICHLER. I really don't know. I would hope so. I would certainly hope so.

Mr. BURR. So we basically are not talking about unsafe products, we are talking about the question of labeling in this particular case where there can be a misunderstanding by the consumer based upon the dynamics of what might be applied.

Mr. EICHLER. Well, I certainly think that anybody could be misled by anything or it is possible that if you are, you could read a label and you could misunderstand that. I agree with that; I think that is possible.

But I think that we have to give the American public—every year we do have a little bit more education and every year we do have a little bit better understanding of what is going on.

Mr. BURR. And I can assure you that we are trying to work with agencies to try to make sure that they change as technology and information gets better.

I am going to pass on the remainder of my time if I can. I really would like to get this finished before we have to leave and as you heard the buzzer, I am going to allow the ranking minority member, Mr. Waxman, to follow up and then, if we can, we will take one on this side and I think we might be able to make our vote.

Mr. WAXMAN. Thank you, Mr. Chairman. I know the Chudas have to leave to catch a flight back to Los Angeles and because of the extra security precautions, they probably need to leave right away.

I just was going to ask you one question.

Doesn't it make just common sense if we are going to have a bill that is going to increase the amount of pesticides that will be on food, if we have a known or probable human carcinogen, even if we are going to allow it because we are going to have this risk/benefit evaluation, shouldn't we let the consumers know, just have that information available to them so those who want to take precautions can avoid it, those who don't won't?

Ms. CHUDA. That is all I am saying is, give us the right to know. If I as a mother during the time when Colette was young would enter the supermarket and I could browse the supermarket and look at various products, be it household chemical type products, the fruits or vegetables that might have contained pesticides that were carcinogens, if these things were labeled as such, if I had a better understanding as a mother as to what it was I was bringing into my household, I might have avoided her cancer from occurring.

I think what we are saying here is let's work together. I understand what you are up against in terms of cost/benefit but there is no risk. If you are talking about the life of a child, there should be no risk. Why can't we create a new paradigm? Why can't we put a child in the center of that paradigm instead of a 150 pound male, which is what most of the tolerances are based on? Why don't we look at a child? Why don't we protect ourselves, all of us?

But I think we know that the pervasive chemicals that are in our environment are cumulative, synergistic and they are affecting the development of children and I think we have to begin with a new trust and that is putting children first.

Mr. WAXMAN. Well, we have several provisions. One is to put children first. But even if we weren't going to do that, one of the provisions we have is people ought to have the information. If we are going to allow these pesticides to be used, let the people know about it.

Mr. Chairman, I want to let anybody else ask any questions of the Chudas before they leave because I know they have to leave early. Then I am going to yield to Mr. Bilbray, because he ought to have a chance since we will probably have to break for a bunch of votes because those Democrats are being dilatory on the floor.

Mr. BURR. I thank the gentleman and the Chair would recognize Dr. Coburn for 1 quick second.

Mr. COBURN. Mr. Chair, I would like to have permission to enter into the record these two studies that I referred to.

Mr. BURR. Without objection.

[The reports appear at pp. 170.]

The Chair would recognize Mr. Bilbray.

Mr. BILBRAY. Yes, I would say this just quickly for those of us who are Californians. There is this sense that you can't have overkill by warning. Now, we live in a State where there might have been a good idea and I ask your dialog. With Proposition 65 and the average citizen in California, they don't even react to those warnings now, and we have reached a point where there's—and I want to say this to our witness. There is a point to where the average mother just tunes out these warnings, and I think we need to make sure that there is balance enough to where we protect the children, but we don't desensitize the consumer with the attitude of whenever in doubt, let's just say it might be bad, and say it because there is nothing to lose.

What I worry about, as somebody who has seen bad things happen, from my family's perspective, is that I watch the average consumer become desensitized to "wolf" being cried all the time. Wouldn't you agree that we have got to make sure that when we do label these things, when we do raise a red flag, that we don't run into a situation where we desensitize them? I think those of us in California, we walk into any store or facility in California and it has got a warning sign that there is cancer-causing elements used or in this area, and do you think the consumer really sees or reacts to those now? You are in California.

Ms. CHUDA. I think you do see them. I have seen them labeled outside of supermarkets concerning saccharin. I don't buy anything that contains saccharin. I think it is a warning and I think it is an important warning and I think it is something that we need. I mean, personally, we have to have the right to choose.

The second point is, where are the alternatives? Where are the companies out there developing something other than a carcinogen or a chemical? Where are the alternatives that could infiltrate our marketplace, create a greater consumer demand? Because I think the populace at large wants that. I think they want products that don't have carcinogens. Why can't we make this country strong and develop products that don't have——

Mr. BILBRAY. My question was specific to Proposition 65.

Ms. CHUDA. Right.

Mr. BILBRAY. Which you and I know we cannot walk into almost any public facility, be it a restaurant, a bar, a grocery store, a hardware store, that we do not have those warnings. But I am saying with Proposition 65, we have been so desensitized, that when you walk into a public facility now, you are probably desensitized to every one of them, because there is an overkill of warning. That is what I was talking about, specifically what has happened in California with Proposition 65.

Mr. WAXMAN. Will the gentleman yield to me?

Mr. CHUDA. There is a particular study right here that talks about under Proposition 65, these exposures—we are not told what exposures to children are under Proposition 65. We know they exist but we don't know what products our children are exposed to.

Mr. WAXMAN. Mr. Bilbray, will you yield to me?

Mr. BILBRAY. Yes.

Mr. WAXMAN. I wanted to clarify something for everybody's information. What we would do would be to preempt Proposition 65 and if we are going to have the underlying bill which would use more pesticides, at least for 12 or 13 pesticides that are probable human carcinogens or known human carcinogens, have the information about those disclosed. That, I think, would have far more meaning because we are not talking about everything being labeled, we are talking about something for which there is a scientific basis.

Now, from my point of view, if it is a known human carcinogen, I don't want it used at all. But if we accept the premise of this bill that we are going to say that even though there is a risk to human health, we are going to let it—the pesticide be used because of the interests of the growers, let the public know about it.

Mr. BILBRAY. Reclaiming my time, the fact is that the issue of zero risk is a great goal. Everyone knows that that sounds good in Washington at a hearing but zero risks do not exist in life, they do not exist for you to come here to testify, for me to take my child to school. And the fact is that what we are looking here is that what is a reasonable, what is a reasonable level of risks based on cost benefit and how those things work out.

But the concept of what we are hearing here, that any reasonable impact at any level is not acceptable, I think those are lines that sound good when we are here. But when we are trying to raise our children, when we are trying to choose, to make priorities of protecting them, we need to know what is reasonable, and make those determinations. And I agree the consumer should know but, again, what has happened many times is that this has been used as an excuse to absolutely walk away from—walk away from the reasonable application of concerns, and then the parent just gets so overwhelmed that they no longer have a rational basis on which to make a decision.

Mr. BURR. The gentleman's time has expired.

The Chair would like to thank the members for their participation today and since this member is not moving as quickly today as he would on a normal day, I am going to try to allow Henry and I at least 5 minutes to get over to vote.

Let me first say how thankful we are to the witnesses that are here.

Your testimonies are very valuable to the decisions that we have got to make and to Ms. Chuda, let me say this as a father of a 10-year-old and a 9-year-old, I'm very concerned about the effects that the decisions that we make have on children because I have got them. Many members up here do, so we are searching through the available information, the new technology, the new data to make sure that the decisions that we work with, that we are able to communicate that into what we plan to do and I again thank each one of you for the ability to hear your testimonies today.

This meeting is adjourned.

[Whereupon, at 3:14 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows.]

Economic Impacts and Environmental and Food Safety Tradeoffs of Pesticide Use Reduction on Fruits and Vegetables

by C. Robert Taylor[1]

Introduction

Perplexing and often exaggerated economic, environmental, and health tradeoffs are involved in pesticide policy. These tradeoffs are especially apparent in pesticide policy related to fruits and vegetables. In an Editorial in *Science* magazine, Philip H. Abelson writes:

> "The public has become increasingly aware that a diet that includes four or five fruits or vegetables per day substantially reduces the incidence of many types of cancers. At present, supplies of these foods are abundant and relatively inexpensive. But continuation of trends in the cancellation (banning) of fungicides could lead to food scarcities. An increase in the contamination of foods by fungal products that include carcinogens and nerve, liver, and kidney poisons would also follow. Moreover, in the absence of protective fungicides, plants in self-defense create phytoalexins, some of which are toxic to humans and induce carcinomas in rodents."

Estimates of the aggregate economic and pesticide residue risk effects of severely restricting use of pesticides on domestically produced fruits and vegetables are presented in this report. Out of necessity the analysis is a broad generalization. First, the policy debate has not matured to the point where any of the major players are willing to define policy options with sufficient detail for them to be subjected to rigorous economic and risk analysis. Second, only a few estimates of the fruit and vegetable yield and production cost consequences of pesticide policies are available. Third, existing data on fruit and vegetable markets (price, acreage, cost and production) are not suited for refined analysis of the food quality dimension of pesticide policy. Nevertheless, adequate information is available to allow estimation of the direction and order of magnitude of the economic impacts and tradeoffs associated with pesticide bans on fruits and vegetables.

Six categories of commodities are considered in this study: fresh, frozen, and dried fruit, and fresh, frozen, and canned vegetables.[2] Policy options highlighted is complete elimination of pesticides used on domestically produced fruit and vegetables, and a 50% reduction in pesticide use. These policies may seem extreme to some people, but they are not out of line with proposals introduced into the U.S. Congress, nor out of line with a strict interpretation of the Delaney Clause that calls for zero tolerance of pesticide residues on processed food.[3] To the extent possible, the effects of the policies on pesticide residues in food are also considered.

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[1] Eminent Scholar of Agriculture and Public Policy at Auburn University. Partial funding from the American Farm Bureau Research Foundation (AFBRF) is gratefully acknowledged. Constructive reviews by Gary Fairchild, Edward W. McLaughlin, Ron Knutson, Ed Smith, John Adrian, Patricia Duffy, Arlen Smith, Terry Francl and Scott Rawlins are also gratefully acknowledged. Estimates of economic impacts presented in this report solely reflect the analyses and views of the author, and do not necessarily reflect the position of the AFBRF, Auburn University or any of the reviewers.

[2] For a discussion of commodities included in these aggregate categories and a discussion of fruit and vegetable data voids, see the USDA report by Putnam and Allshouse.

[3] Also, minor use pesticides, many of which are used on fruit and vegetables, are slowly being withdrawn from the market under present legislation, with possibly large cumulative effects on production. Gianessi and Puffer state:

Two extensive programs for sampling pesticide residues in fruit and vegetables were conducted in 1992. One was done by the U.S. Food and Drug Administration (FDA) Pesticide Program as part of its residue monitoring and enforcement program, and the second was done by the USDA (1994) Agricultural Marketing Service Pesticide Data Program (AMS PDP). The AMS PDP survey was for 10 fresh fruits and vegetables monitored in 1992 in California, Florida, Michigan, New York, Texas and Washington. The FDA program was directed toward enforcing tolerances and thus may not be an unbiased sample, while the AMS PDP program was intended to be unbiased but used more sensitive laboratory techniques and was thus able to detect more residues than in the FDA analysis.[4]

Results of the FDA sample are shown in Figure 1 for domestic and imported fruits and vegetables. A majority of the samples had no detectable residues. Although imported fruit and vegetables had a slightly lower level of detectable residues, they also had a higher percentage of samples with residues that violated FDA tolerance standards. FDA estimates weighted by consumption from domestically and imported fruits and vegetables, show that an average of 1.84% of all fruits and vegetables violate standards.[5]

The results of the AMS PDP sample, which utilized more sensitive laboratory techniques, provided a somewhat surprising result. In this study the percentage of residues that exceeded tolerances is 1.1%, below the 1.84% in the FDA study. Because of sampling design, the AMS PDP study may be more representative than the FDA study.

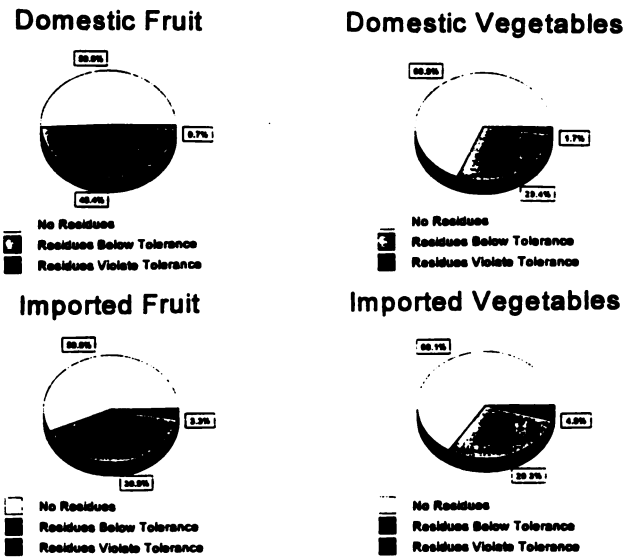

Figure 1. Pesticide Residues in FDA Samples.

"As reregistration of pesticides proceeds, many minor use registrations are being voluntarily withdrawn by the registrants. Lack of market incentive and fear of liability hinders the registration of new chemicals for minor uses. Consequences to growers of fruits and vegetables from limited choices in pest control chemicals will include higher costs for pesticides, greater risk of crop losses, increased problems with resistant pests, and disruption of successful Integrated Pest Management Programs.... As yet, public policy on pesticides has notfocused on the pest control needs associated with minor uses."

[4] Factors considered in the FDA sampling plan included recently generated FDA residue data, regional intelligence on pesticide use, chemical characteristics and toxicity of the pesticide, and other factors. In addition, FDA allowed for discretionary analyses.

[5] The FDA average was calculated by weighting residues by consumption from domestically and imported fruit and vegetables.

The USDA (1995) assessment of the AMS PDP study is especially interesting because it states that the majority of preharvest pesticides tested in the PDP did not leave detectable residues, even with their highly sensitive tests. The few pesticide that were detected were near the level of negligible risk were either banned long ago (DDT and DDE), or are chemicals used in *post*harvest processing of fruit and vegetables.

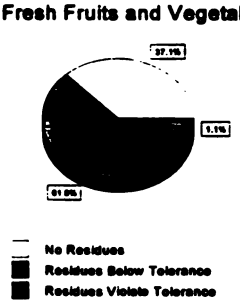

Figure 2. Pesticide Residues in 1992 AMS PDP Samples.

The FDA data also show that pesticide residues in domestically produced and imported fruits and vegetables differ. Changes in domestic pesticide policy may change pesticide residues in food grown in the U.S., but residues on imported food cannot be ignored. Imports account for over 15% of all fresh and processed fruit and vegetables consumed in the U.S., and a much higher percentage during off season. Imports are influenced by a variety of factors such as foreign exchange rates, but the import share of domestically consumed food can be indirectly influenced by pesticide restrictions in the U.S. Thus, induced changes in the import share of domestically consumed food (and pesticide residues) should be considered in making domestic pesticide policy.

A USDA (1995) analysis of the AMS PDP data combined residue estimates with food consumption data to estimate pesticide intake for average adults and average 1-year old children. They considered both threshold and nonthreshold pesticides in defining negligible risk.[6] FDA conducted a similar total diet study. Both the ERS and FDA studies concluded that dietary intakes of pesticide residues were well below established standards. Nevertheless, reduction in pesticide use remains a hot policy topic, perhaps because of factors such as (a) the public's fear of pesticides and other chemicals, (b) distorted media hype, and (c) allegations about environmental and wildlife damages.

SPECIFIC PESTICIDE ALTERNATIVES ANALYZED

Analysis of the aggregate economic effects of pesticide policy requires information on how per-acre crop yields and production costs are impacted by the policies considered. A recent study by Knutson, Hall, Smith, Cotner and Miller (1993, 1994) is the most comprehensive review currently available and is used as a source of yield and cost estimates on which to base the following aggregate economic analysis.[7]

Pesticide policy options to be evaluated must be consistent with yield and cost estimates used for the study. Since the Knutson, et al, study was used for yield and cost estimates, analysis is restricted to 50% reduction and total elimination of pesticides used on domestically produced and processed fruit and vegetables. The policy alternatives analyzed here are (1) a 50% reduction in pesticides (herbicides, insecticides, miticides, and fungicides) used on domestically produced fruits and vegetables, (2) complete elimination of pesticides used on domestically produced fruits and

[6] Quoting from the USDA (1995) study, "Threshold pesticides are those for which very low levels of exposure (up to the threshold quantity) cause no ill effects. Nonthreshold pesticides are those for which there is no positive exposure level that is risk free... For nonthreshold pesticides, negligible risk is defined as the level of pesticide intake that would lead to a 70-year lifetime risk of 1 cancer case per million. For threshold health effects, the negligible risk level is the Reference Dose determined by EPA. The Reference Dose is generally 100 times lower than the maximum dose that has no health effects on experimental animals."

[7] This study, like most studies of yield and cost effects of pesticide policy, is not without controversy (see, e.g., Smith).

vegetables, and (3) complete elimination of pesticides used on domestically produced fruits and vegetables, with a ban on all imports of fresh and processed fruit and vegetables into the U.S.

The first two options allow for imports of fruit and vegetables, even if they have pesticide residues. The latter option is included because if the purpose of a pesticide ban is to reduce or eliminate pesticide residues on food, then the issue of residues on imported food must be addressed. Broadly defined policy options for imported foods are to (a) require countries that export to the U.S. to guarantee that the food products are residue free, either by testing for residues or by imposing production constraints like those imposed on domestic production and processing, (b) have the FDA or another U.S. Agency test imports for residues, and (c) ban imports of all fruit and vegetables. The first import policy would be difficult to implement. The second policy would be quite costly, because it is very expensive to test for pesticide residues and this type of policy might require testing a large sample to insure compliance. The third policy is incompatible with GATT, but consistent with many past agricultural policies, here and in many other countries. Analysis of the first two import scenarios is beyond the scope of this study, while the import ban is more easily evaluated. Economic impacts of the import ban are expected to be broadly indicative of the magnitude of impacts of the other two options.

PRODUCTION COST IMPACTS

Estimates of how per-unit costs change under each policy draw heavily from the study by Knutson, et al. This study relied on scientists to estimate the crop yield and production cost consequences of the pesticide policy scenarios.

The Knutson, et al, study was for specific types of fruits and vegetables in different growing areas, but did not have full coverage of all commodities in all possible growing regions in the U.S. From the Knutson, et al, study it is apparent that severe pesticide restrictions would have yield and cost consequences that differ considerably from one growing region to another. Thus, production would be expected to shift to areas with lower unit cost.

Because of incomplete crop and area coverage of the Knutson, et al, study and anticipated regional shifts in production, some judgement was required to translate their yield and cost consequences into per-unit cost changes for the six categories of fruits and vegetables considered here. Estimates of the unit cost consequences of a 50% reduction and total elimination of pesticides (based largely on the Knutson, et al, study, but considering anticipated regional shifts) are shown in Table 1. For all fruits and vegetables taken together, unit costs would increase by 30% and 75%, respectively for a 50% reduction and complete elimination of pesticide use. These cost changes correspond roughly to 25% and 60% yield reductions, respectively.[8]

Table 1. Estimated Effects of Pesticide Use Restrictions on Per-Unit Production Costs*

[Percentage Increase in Unit Cost]

Commodity	A 50% Reduction in Pesticide Use	Total Elimination of Pesticide Use
Fresh Vegetables	40	90
Frozen Vegetables	20	45
Canned Vegetables	20	45
Fresh Fruit	30	100
Frozen Fruit	25	80
Dried Fruit	25	80
Weighted Average for All Fruits & Vegetables	30	75

*The percentage cost increases apply to total production costs.

DEMAND AND SUPPLY RELATIONSHIPS

Econometric estimates of demand and supply relationships for the six fruit and vegetable aggregates (fresh, frozen, and dried fruits, and fresh, frozen, and canned

[8] It should be noted that comparing "percentage yield" changes with "percentage unit production cost" changes may be deceptive. For example, if per-acre production costs do not change with a pesticide ban that reduced yield by 50%, unit production costs would increase by 100%. Because these percentage effects are so different, it may inappropriately appear that the yield estimates are being exaggerated by use of unit cost changes.

vegetables) are summarily expressed in terms of elasticities in Table 2.[9] The elasticities show the percentage change in quantity with respect to a 1% change in price. For example, a 2.7% change in production of fresh vegetables would result from a 10% change in the wholesale price of fresh vegetables (Table 2). All of the elasticities in Table 2 are for a wholesale prices paid index (PPI). Theoretically, these elasticities pertain to a "long-run" time period in which all dynamic adjustments to the pesticide policy have occurred. However, since demand and supply estimates were based on 15 years of data or less, these elasticities may be more appropriately viewed as pertaining to intermediate-run adjustments, say the economic effects ten years after implementation of the pesticide policy.

Table 2. Long Run Production, Export Demand, Import supply and Domestic Consumption Price Elasticities*

Commodity	Production	Export Demand	Import Supply	Domestic Use
Fresh Vegetables	0.27	−0.90	0.15	−0.22
Frozen Vegetables	0.87	−0.88	0.17	−0.33
Canned Vegetables	1.34	−0.34	0.76	−0.26
Fresh Fruit	0.43	−0.45	0.07	−0.21
Frozen Fruit	1.16	−0.01	0.92	−0.41
Dried Fruit	0.35	−0.35	1.11	−0.61

*All of the elasticities are relative to wholesale (PPI) prices.

Since production of fruits and vegetables is competitive, individual producers cannot strictly "pass-on" production cost increases to consumers. However, the market, through supply and demand adjustments, would pass at least part of the unit cost increases on to consumers. With full long-run adjustments, say over a period of 20 or more years, we would expect most if not all of the cost increases to be passed on to consumers. Since this study pertains to an intermediate run period, the estimates of price impacts are conservative from a longer-run perspective.

Effects of pesticide bans on supply were estimated by shocking the PPI by an amount appropriate for the policy and commodity group.[10] For example, if the ban would result in a 20% unit cost increase, then the quantity supplied at a PPI (index value) of 120 with the pesticide ban would be the same as the quantity supplied in the baseline (current pesticide policy) at a PPI of 100.

The aggregate economic impacts of pesticide bans on prices and quantities were based on the notion of an expected market clearing price (PPI) at which domestic production plus imports was equal to domestic consumption plus exports. Changes in economic variables were computed as deviations from market clearing prices and quantities assuming continuation of present pesticide use practices and current foreign exchange rates.

The economic model centered on the PPIs for each of the six commodity aggregates. To estimate consumer price effects, the relationship between wholesale and retail prices were established. These relationships are expressed in terms of price transmission elasticities, as shown in Table 3. In a short-run scenario, retail prices are expected to increase by about the same percentage as wholesale prices. However, over time, competitive pressure might pull retail prices down to where they exceeded wholesale prices by a constant absolute (rather than percentage) marketing margin. Thus, with adjustments, retail prices would be expected to increase by a smaller percentage than grower prices or wholesale prices. For example, a 1% increase in the wholesale price translates into a 0.20% increase in the retail price of fresh vegetables (Table 3). Many fresh fruits and vegetables have higher marketing margins compared to processes products because of short shelf life and other factors. These higher marketing margins usually translate into lower price transmission elasticities, as is reflected in the estimates in Table 3.

Because economic impact estimates are for very broadly defined commodity groups, it should be recognized that impacts for individual commodities, such as fresh apples or orange juice, can be much less than or much more than the aggregate estimates. However, elasticities estimated for the group are typically less than own-price elasticities for individual commodities because the aggregation masks substitution possibilities.

[9] Readers interested in specific econometric results and statistics should contact the author.

[10] Time-series data were not available on per-unit or per-acre production costs under present pesticide use practices. Thus, the supply analysis had to be based on output price only rather than on yields and costs or on expected net returns. Since real per-acre production costs and yields of most crops appear to have remained fairly stable over the past ten years, basing supply on output price does not appear to introduce a severe bias in the econometric estimates.

Table 3. Long-run Price Transmission Elasticities

Commodity	Elasticity*
Fresh Vegetables	0.20
Frozen Vegetables	0.62
Canned Vegetables	0.40
Fresh Fruit	0.43

*Percentage change in the Consumer Price Index (CPI), which is a retail price index, associated with a 1% change in the Producer Price Index (PPI), which is a wholesale price index. CPI data for processed fruit were not available; thus no elasticities were available.

AGGREGATE ECONOMIC EFFECTS

Estimates of the aggregate economic effects of a 50% reduction in pesticide use compared to current use levels are given in Table 4. Wholesale prices would increase by 9 to 19%, depending on the commodity group. Estimates in Table 4 show that about ⅓ to ⅔ of the production cost increase would be passed on to wholesale prices. For example, the 40% unit production cost increase for fresh vegetables would result in a 17.7% increase in wholesale price after market adjustments, thus passing on somewhat less than one-half of the production cost increase.

Table 4. Estimated Price, Supply, and Utilization Effects of a 50% Reduction in Pesticide Use with No Import Restriction

[Percentage Changes]

Commodity	Increase in per unit production cost	Production	Exports	Imports	Domestic Use	Wholesale Price (PPI)	Retail Price (CPI)
Fresh Vegetables	40	-6.0	-15.9	2.6	-3.9	17.7	3.5
Frozen Vegetables	20	-5.0	-12.6	*-8.4	-4.7	14.3	8.9
Canned Vegetables	20	-5.4	-5.4	20.3	-4.1	15.9	6.4
Fresh Fruit	30	-7.5	-8.7	1.4	-4.0	19.3	8.3
Frozen Fruit	25	-8.7	-0.1	16.2	-7.1	17.5	NA
Dried Fruit	25	-5.6	-3.2	10.0	-5.5	9.1	NA

*Frozen and canned vegetable import supply equations both had cross-price effects. The negative sign on imports of frozen vegetables can be attributed to these cross-price effects combined with own price effects. Imports of frozen and canned vegetables taken together increase, as expected.

Depending on the product type, retail prices would increase by 3% to 9%, which is a much smaller percentage increase than for wholesale prices. Associated with the price increases, domestic consumption declines 4% to 7%. Domestic production declines by a higher percentage than consumption, because of the export and import adjustments shown in Table 4.

Estimated economic effects of total elimination of pesticide use in the U.S., with imports allowed, are shown in Table 5. Depending on the commodity group, wholesale prices would increase by 29% to 64%, and retail prices would increase by 8% to 28% as a result of market adjustments to assumed unit production cost increases of 45% to 100%. Export decreases would range up to 30% and import increases would range up to 52%. Domestic use of fruits and vegetables are estimated to decline by 7% to 23%.

Table 5. Estimated Price, Supply, and Utilization Effects of Total Elimination of Pesticide Use on Fruit and Vegetables, with No Import Restriction

[Percentage Changes]

Commodity	Increase in per unit production cost	Production	Exports	Imports	Domestic Use	Wholesale Price (PPI)	Retail Price (CPI)
Fresh Vegetables	90	-11.2	-29.9	4.9	-7.3	39.7	7.9
Frozen Vegetables	45	-11.1	-28.3	-18.8	-10.6	32.2	20.1
Canned Vegetables	45	-12.2	-12.2	45.6	-9.2	35.9	14.3
Fresh Fruit	100	-24.9	-29.1	4.7	-13.4	64.3	27.6
Frozen Fruit	80	-27.7	-0.4	51.8	-22.7	56.0	NA
Dried Fruit	80	-17.9	-10.1	32.1	-17.7	29.0	NA

Zilberman, et al, estimated the economic impacts of banning pesticides used in producing five fruit and vegetable crops in California. Their price change estimates ranged from 13% to 175%, depending on the crop and whether the yield impact was assumed to be average or high. Since effects on individual commodities can be higher or lower than for aggregates, their results seem reasonably consistent with those given in Table 5.

Table 6 presents estimates of the effects of totally eliminating pesticide use in the U.S., while also banning imports. Wholesale prices are estimated to increase from 37% to 122%, and retail prices are estimated to increase from 11% to 53% with this drastic policy.

Table 6. Estimated Price, Supply, and Utilization Effects of Elimination of Pesticide Use on Fruit and Vegetables Combined with a Ban on Imports of Fruit and Vegetables

[Percentage Changes]

Commodity	Increase in per unit production cost	Production	Exports	Imports	Domestic Use	Wholesale Price (PPI)	Retail Price (CPI)
Fresh Vegetables	90	-9.3	-49.9	-100.	-12.2	55.3	11.0
Frozen Vegetables	45	-0.3	-39.2	-100.	-14.7	44.6	27.8
Canned Vegetables	45	-6.2	-13.8	-100.	-10.4	40.4	16.1
Fresh Fruit	100	-0.2	-55.3	-100.	-25.5	122.4	52.5
Frozen Fruit	80	-18.5	-0.5	-100.	-26.0	64.0	NA
Dried Fruit	80	-14.9	-13.1	- 100.	-22.9	37.4	NA

As noted previously, there is uncertainty about the crop yield and unit production cost impacts of pesticide policies. Table 7 provides estimates that might assist readers who want to examine other fruit and vegetable pesticide policies, or who have different estimates of unit cost effects of the policies considered here. This table shows the percentage economic effects associated with 10% increases in unit production costs. For example, a 10% increase in production costs for fresh vegetables would increase wholesale prices by 4.4% and retail prices by 1.0%. For a 20% increase in unit costs, these price increases should be doubled.

Table 7. Estimated Effects of a Ten Percent Increase in Per Unit Production Costs on Consumption and Prices, Allowing for Market Adjustments

[Percentage Changes]

Commodity	Increase in per unit production cost	Wholesale Price	Retail Price	Production	Export Demand	Import Supply	Domestic Use
Fresh Vegetables	10	4.4	1.0	-1.5	-4.0	0.6	-1.0
Frozen Vegetables	10	7.2	4.5	-2.5	-6.3	-4.2	-2.4
Canned Vegetables	10	8.0	3.2	-2.7	-2.7	10.1	-2.1
Fresh Fruit	10	6.4	2.8	-2.5	-2.9	0.5	-1.3
Frozen Fruit	10	7.0	NA	-3.5	-0.1	6.5	-2.8
Dried Fruit	10	3.6	NA	-2.2	-1.3	4.0	-2.2

HEALTH AND ECONOMIC TRADEOFFS

A few of the basic economic and pesticide residue tradeoffs involved in fruit and vegetable pesticide policy are presented in Table 8. A 50% reduction in pesticide use is estimated to increase unit production costs by 30%. With intermediate-run equilibrium market adjustments, wholesale prices would increase by 17%. Unit gross returns to producers would decrease by 13% (Computed as a 30% unit cost increase minus a 17% price increase). Domestic production would decline by 6%. Retail prices for food and vegetables would increase by 9% and consumption would decrease by 4%. Production changes combined with per-acre yield changes underlying the unit cost increases suggest that acreage used for production of fruit and vegetables in the U.S. would increase by about 1 million acres. This fruit and vegetable acreage expansion would largely displace other crops, some of which would move to marginal, more erosive cropland. To the extent that this happens, erosion, sedimentation and related problems may become worse with a fruit and vegetable pesticide restriction.

Complete elimination of pesticides used in the U.S. would increase wholesale prices by 45% based on a 75% increase in unit production costs. Gross returns to domestic producers would thus decrease by 30%. Retail prices would increase by 27% and consumption would decrease by 11%. Acreage required for production of fruit and vegetable crops in the U.S. would increase by about 44%, or 2.5 million acres with the ban.

Table 8. Impact of Pesticide Policies on Key Economic Indices for All Fruits and Vegetables

[Index Values]

Item	Baseline (current pesticide Use)	50% Reduction in Pesticide Use in the U.S.	Elimination of Pesticide Use in the U.S.	Elimination of Pesticide Use in the U.S. with an Import Ban
Per-Unit Production Costs	100	130	175	175
U.S. Production	100	94	84	94
Exports	100	90	73	56
Imports	100	103	107	0
Domestic Consumption	100	96	89	84
Wholesale Price (PPI)	100	117	145	168
Retail Price (CPI)	100	109	127	145
Violative Pesticide Residues	100 (1.84%)	NA	24 (0.44%)	0

Also shown in Table 8 are estimates of the effects of the policies on pesticide residues that violate FDA standards. These estimates are based on FDA pesticide residue monitoring data, and the mix of domestic consumption from imports and domestically produced fruit and vegetables shown previously. With current pesticide use patterns, over 60% of the FDA samples had no residues, 1.84% of domestically consumed fruits and vegetables violated residue standards, and the remainder had residues that did not violate standards. It is not clear how residues would be impacted with the 50% pesticide use restriction because no estimates of how residues in domestically produced fruit and vegetables have been made. However, with complete elimination of U.S. pesticide use, the percentage of fruit and vegetables that violate residue standards would decline from 1.84% to 0.44%, and decline to zero if imports of fruits and vegetables were banned along with elimination of U.S. pesticide use.

As Abelson notes, however, there would be adverse indirect food safety consequences of severely restricting or banning pesticide use in terms of increased contamination by fungal products and by phytoalexins created in self-defense by plants. Another potential adverse side effect is that the increased acreage resulting from a ban on all pesticides used in major field crop production along with pesticides used on fruit and vegetables would increase acreage under cultivation by about 33 million acres.[11] This acreage expansion would occur on marginal land and would increase erosion and sedimentation, increase use of fertilizer and energy, and reduce wildlife habitat, but would have positive benefits to (non pesticide) agricultural input suppliers and some other sectors of the economy. Direct impacts of pesticide use restrictions on wildlife and other environmental factors, excepts those noted above, are beyond the scope of this study.

CONCLUDING REMARKS

There have been several recent legislative proposals which call for severe restrictions on pesticide use, and a Court of Appeals decision that has called for strict enforcement of the Delaney "zero tolerance" Clause. With such severe restrictions on pesticide use, fruit and vegetable producers' income would fall, consumers would pay more for food and consume fewer fruit and vegetables needed in a balanced diet. In addition, there would be indirect effects, including an increased health risk from nonpesticide sources, and an expanded crop acreage would increase erosion and

[11] Since the highest quality land is often used for fruit and Vegetable production, much of the acreage expansion would be with field crops and would occur on marginal agricultural land. Land in fruit and vegetable production would increase about 3 million acres, and land in production of major field crops (feed grains, food grains, cotton, peanuts, rice and hay) would increase about 30 million acres with the ban extended to all pesticides used in agricultural production. For a discussion of restricting pesticides used on major field crops, see Taylor, Penson, Smith and Knutson.

sedimentation and decrease wildlife habitat. The recent FDA studies concluded that dietary intakes of pesticide residues were well below established standards, and USDA studies (1994, 1995) corroborated this finding. Thus, pesticide use restrictions on fruit and vegetable production and processing would have extremely small or even infinitesimal effects on pesticide residues in food.

Significant adverse economic effects and some unintended adverse side-effects on health compared to extremely small roductions in pesticide residues in fruits and vegetables bring into serious doubt the social desirability of severely restricting, from a food safety viewpoint, pesticide use in fruit and vegetable production and processing. Environmental and wildlife benefits of pesticide use restriction are largely beyond the scope of this study. However, this study shows that increased erosion and roduced land available for wildlife would occur from severe pesticide use restriction. These paradoxical aggregate effects on the environment and wildlife need to be weighed against any possible benefits when evaluating pesticide policy from an environmental standpoint.

Rather than severely restricting pesticide use, as called for in several recent legislative proposals and in the Court's interpretation of the Delaney Clause, pesticide policy attention would appear to be better directed toward (a) lowering costs of developing and registering or reregistering safe pesticides, particularly those used on fruits, vegetables, and other minor crops, (b) increasing the efficiency of identifying individual pesticides that pose health, environmental or worker safety problems, (c) eliminating the fragmentation of pesticide regulations in Federal and State government, (d) taking a balanced view of risk, considering all sources of risk and the economic adjustments to price and risk changes, and (e) increasing adoption of integrated pest management (IPM) and nonpesticide control options.

REFERENCES

Abelson, Philip H. "Adequate Supplies of Fruits and Vegetables." *Science.* Vol. 266, November 25, 1994.

Food and Drug Administration, "Food and Drug Administration Pesticide Program: Residue Monitoring, 1992." Published in the *Journal of AOAC International,* Vol. 76, September/October, 1993.

Gianessi, Leonard P., and Cynthia A. Puffer. "Registration of Minor Use Pesticides: Some Observations and Implications." *Agricultural Resources: Inputs Situation and Outlook Report.* USDA, Economic Research Service, AR-25, February 1992: 52-60.

Knutson, R.D., C.R. Hall, E.G. Smith, S.D. Cotner, and J.W. Miller, *Economic Impacts of Reduced Pesticide Use on Fruits and Vegetables,* American Farm Bureau Foundation, 1993.

Knutson, R.D., C.R. Hall, E.G. Smith, S.D. Cotner, and J.W. Miller, "Yield and Cost Impacts of Reduced Pesticide Use on Fruits and Vegetables," *Choices,* First Quarter, 1994: 15-18.

Putnam, J.J., and J.E. Allshouse, *Food Consumption, Prices and Expenditures, 1970-90,* USDA/ERS Statistical Bulletin No. 840, August 1992.

Smith, Katherine Reicheiderfer, "Science and Social Advocacy: A Dilemma for Policy Analysts," *Choices,* First Quarter, 1994: 19-24.

Taylor, C.R., J.B. Penson, Jr., E.G. Smith, and R.D. Knutson, "Economic Impacts of Chemical Use Reduction on the South," *Southern Journal of Agricultural Economics,* July 1991: 15-23.

United States Department of Agriculture, *Agricultural Resources and Environmental Indicators,* USDA/ERS/NRED Agricultural Handbook No. 705, 1995: 102-5.

United States Department of Agriculture, *Pesticide Data Program (PDP): Summary of 1992 Data,* USDA/AMS, April 1994.

Zilberman, D., A. Schmitz, G. Casterline, E. Lichtenberg, and J.B. Siebert, "The Economics of Pesticide Regulation," *Science,* Vol. 253, August 1991: 518-22.

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ORGANOCHLORINE RESIDUES AND RISK OF BREAST CANCER

Introduction

Considerable attention has recently been focused on the possible role of estrogenic organochlorine compounds such as DDT, and its primary metabolite DDE, as etiologic agents in the development of human breast cancer[1-4]. While the biological plausibility of the hypothesis is derived from the estrogenic activity of these compounds, a causal relationship remains to be established.

The most recent of these studies, and the largest to date, investigating the association between exposure to organochlorine compounds and the development of breast cancer, failed to demonstrate an association between serum DDE and PCB levels and risk of developing breast cancer[1]. Regrettably, few other large prospective studies utilizing extensive matching of cases and controls have been conducted.

This review exhaustively examines the available scientific literature regarding the possible association between exposure to organochlorine pesticides in general, and DDT specifically, and the development of human breast malignant neoplasms.

Incidence

Breast cancer is the most frequently diagnosed cancer among women of affluent countries (primarily North America and Western Europe). The average lifetime risk of a woman who lives to age 85 has increased from 1 in 20 in 1960, to 1 in 9 today[5,6]. In Canada, there were 11,500 new cases and 4,600 deaths from breast cancer in 1988. In 1993, 16,300 new cases were diagnosed and 5,400 women lost their battle with this disease[7].

The U.S. National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) Program, reports that newly diagnosed cases increased at an annual rate of 1% between 1950 and 1979. This rate increased to 3% per year from 1980-1984[8]. Glass and Hoover[9] reported the largest increases in incidence have occurred in women aged 60 and older (74%), and in those aged 45-59 (36%). In women 20-44 years of age, the rate has remained essentially unchanged. Less than one-third of the overall 15.3% increase in the age-adjusted rate for invasive breast cancers seen between 1972 and 1985 could be attributed to the use of screening mammography.

Tumours of the breast can be categorized according to the estrogen receptor content. (ER-negative tumours are capable of binding 10 femtomole or less of tritiated estradiol/mg of cytosolic protein, while estrogen receptor positive tumours bind greater than 10 fmol/mg of protein). Receptor assays on the tumours of the women in the Glass and Hoover study indicated the incidence of estrogen receptor-negative cancers rose 22-27% between the mid-1970's and mid-1980's, while the number of estrogen receptor-positive tumours increased an average of 131%. It is possible that external hormonal influences could be responsible for the differential rise in estrogen receptor-positive breast tumours.

Mortality from breast cancer has not increased as rapidly as the incidence, possibly due to an increase in the frequency of estrogen receptor positive tumours which carry a better prognosis, and improvements in therapy regimes (chemotherapy and the antiestrogen tamoxifen)[10].

The Role of Estrogen in the Female Body[11,12]

In order to understand how the estrogenic activity of DDT and its metabolites could be related to the development of breast cancer, it is important to consider the role of estrogen in the body. The primary estrogen secreted by the ovaries is 17B-estradiol. Small amounts of estrone are also secreted. Both estradiol and estrone are oxidized in the liver to produce the weak estrogen estriol. The estrogenic potency of estradiol is 12 times that of estrone and 80 times that of estriol. Progesterone is the primary progestin secreted.

Estrogenic hormones stimulate target cells to synthesize enzymes, transport and structural proteins. They enter the cytoplasm of the target cell where they bind with a specific receptor protein. The receptor protein-hormone complex then diffuses into, or is transported into, the nucleus. The complex binds to DNA which activates the transcription process of specific genes to form messenger RNA. Messenger RNA diffuses into the cytoplasm where it promotes the translation process at the ribosomes forming new proteins.

The primary function of estrogen is to cause cellular proliferation and growth of tissues related to reproduction. In the breasts, it causes the development of stromal tissue, the growth of an extensive ductile system and the deposition of fat. At menopause, the ovaries stop secreting estradiol, estrone and

progesterone. Estrogens can be carcinogenic if levels are not kept in check by progesterone, which actually protects premenopausal women from this effect.

Risk Factors for Breast Cancer

There are several established risk factors for breast cancer. A family history of the disease, especially in a first degree relative diagnosed at a young age, predicts a relative risk of between 1.5 and 6.0, depending on the number of first degree relatives afflicted. The risk is greater if the cancer was bilateral[10]. Similarly, women with a history of benign breast disease (atypical hyperplasia) have about four times the risk[13]. Genetics, however, accounts for only 10% of breast cancers in the U.S.[6]

Many of the other important risk factors appear to be related to life-time exposure to estrogen, which stimulates both normal and abnormal breast cell development[14-18]. Women who have undergone ovariectomy prior to age 35 have rates of breast cancer similar to those of men (<1% of breast cancer deaths). Early menarche, nulliparity, late age at first birth and late onset of menopause, increase the risk of breast cancer[19]. Some studies have implicated oral contraceptives as risk factors[19-21], while others indicate no associated risk[22]. The association between the use of oral contraceptives and the development of breast cancer may simply be that these drugs allow women to delay pregnancy until a later age. Similarly, the use of estrogen replacement therapy in postmenopausal women has also been reported to increase risk[16, 23-26].

Exposure to ionizing radiation, especially between puberty and 20 years of age can substantially increase the risk of developing breast cancer[27-28]. Fat content in the diet and its relationship with this disease has been the subject of controversy over the last ten years. There is as much evidence for high fat diets being a risk factor as there are against[16, 29-34]. Not as strongly associated are obesity, in postmenopausal women only, and increased alcohol consumption[10]. Lactation has been found to reduce the risk among premenopausal women in some studies[35-36], but not in others[31,37] and increased physical activity reduced risk in one study of athletes, but not in another[10].

Known risk factors account for approximately 30% of breast cancers. Recent attention therefore, has focused on the possibility that environmental carcinogens may be responsible for the remaining 70%[3]. Some researchers[3,4,38] have postulated that the estrog activity of DDT and its metabolites, could be related the development of this disease. Estrogens are known to stimulate genetically altered breast cells to divide, producing a tumour[13], therefore, chemicals possessing estrogenic activity, such as o,p'-DDT, may increase breast cancer risk simply by increasing cell division. Risk factors associated with intake of high levels of dietary fat may have little relation to fat levels per se, but rather to high concentrations of lipophilic organochlorine compounds[4].

Review of the History of DDT

The insecticidal activity of DDT was identified in 1939 and, by 1943, commercial production had begun. DDT was widely used in agriculture and in public health programs to control vectors of such diseases as malaria, typhus, yellow fever, encephalitis and chagas. US production was greatest in 1963 when 82 million kg were produced. As of 1990, DDT was still being produced in Italy, India, Indonesia and China.

Technical DDT contains 63-77% para,para'-DDT and 8-21% ortho,para'-DDT, as well as lesser concentrations of the following metabolites: para,para'-TDE, ortho,para'-TDE, para,para'-DDE, ortho,para'-DDE and approximately 3.5% unidentified products. All of these compounds are lipophilic.

Estrogenic Activity

The estrogenic activity of DDT isomers and metabolites has been extensively studied. o,p'-DDT competitively inhibits the binding of estradiol to the rat uterine estrogen receptor[39-41], and to estrogen binding protein in induced rat mammary tumours[42], and in human mammary and uterine tumours[43]. It enhances production of an estrogen inducible protein by interacting with the uterine estrogen receptor in the rat[44]. Estrogen receptors from different anatomical locations have been shown to have 1/ 2,000[40,45] to 1/10,000[46] (Kupfer and Bulger, 1976) the affinity for o,p'-DDT as for 17B-estradiol. In vivo dose-response curves to the pesticide are three to four orders of magnitude to the right of those for the hormone[42,45,46]. o,p'-DDT was also shown to support the growth of cloned malignant cells (MT2 cell line) from an estrogen responsive rat mammary carcinoma, at a rate similar to 17-B-estradiol[49]. p,p'-DDT[50], p,p'-DDE[51], the metabolite detected in the more recent studies and o,p'-DDE[52] however, were found to have weak, if any, estrogenic activity.

While these results cannot be directly extrapolated to humans, the data suggest that hyperplastic responses of estrogen-sensitive tissues may be a toxic effect of o,p'-DDT.

Evidence of the Carcinogenicity of DDT

The evaluation of the carcinogenicity of DDT is complicated by the fact that it is stored in adipose tissue, both as the parent and its metabolites. In a variety of short-term tests DDT and DDE were not mutagenic. The International Agency for Research on Cancer (IARC) concluded that there was inadequate evidence for carcinogenic activity in short-term tests[53].

Chronic 2-year feeding studies in rats at dietary levels of 100-800 ppm however, indicated that technical DDT caused "low grade" hepatic-cell carcinomas and hyperplastic liver nodules. In mice, both oral and subcutaneous administration of DDT produced liver tumours. As a class, the organochlorines have long been associated with liver tumours in mice, although this effect has never been demonstrated in humans. DDT was not carcinogenic in hamsters, while DDE only weakly induced chromosomal aberrations in cultured rodent cells. IARC concluded that there was adequate evidence that DDT was carcinogenic in laboratory animals[54]. It also impaired reproduction and/or development in rabbits, birds, dogs and rodents.

Epidemiological Evidence of Carcinogenicity

An epidemiological review conducted by IARC in 1985[53], concluded that "insufficient case-control studies existed for evaluation and therefore assessment of the carcinogenicity of DDT was dependent on inferences from descriptive epidemiology". The IARC review concluded that DDT has had no significant impact on human cancer patterns and is unlikely to be a carcinogen at historical exposure levels. No association was found between exposure to DDT and liver cancer in the only study designed to examine this endpoint[53].

Limitations in available epidemiological studies, such as small sample sizes, lack of consideration of confounding factors and other chemical exposures, and inconsistent results, make an evaluation of the data difficult. Particularly noteworthy, is that few if any of the workers in the DDT production plants where exposures were high and where many epidemiological studies were conducted, were women.

Wassermann et al.[56] examined organochlorine concentrations in malignant breast tissue compared with adjacent normal adipose and glandular tissue. Only nine cases and five controls were used in this study, however, the results indicated that o,p'-DDT concentrations were higher in the malignant tissue. The largest concentration of total DDT and PCBs in cancer patients was also found in the malignant tissue.

Unger et al.[57] examined organochlorine levels (DDE and PCBs) in 14 breast fat samples from breast cancer patients and 18 samples from deceased breast cancer patients. These samples were compared with 21 similar specimens from non-cancer patients and 35 from non-cancer autopsy specimens. The results indicated that there were no statistically significant differences and the authors concluded that human mammary tissue was not a target for PCB and DDE induced carcinogenesis. They also speculated that the higher level of PCBs detected in the adipose tissue taken from the deceased patients may have been due to pre-death starvation and the mobilization of adipose tissue and its contents.

A 10 year prospective follow-up study of 919 men and women whose serum DDT levels were measured in the mid-1970s, indicated no consistent dose-response relationship existed between cancer mortality rates and serum DDT levels[58]. In fact, the mean level of serum DDT was lower among subjects who had died of various types of cancer, than it was among those who had not. The only suggestive relationship that appeared in this study, was a weak dose-response relationship between serum DDT levels and respiratory cancer mortality which was not statistically significant.

Westin and Richter[59] suggested a decline in breast cancer mortality rates in Israel between 1976 and 1986, despite increases in a number of risk factors among Israeli women, was due to the banning of organochlorines from dairy barns in 1978. Their hypothesis however, failed to address why the reported decline began two years *prior* to the ban being imposed and why a steep rise in breast cancer mortality did not occur subsequent to the introduction of these pesticides and following a sufficient latency period.

The same year a Finnish study[60] which examined residues of polycyclic aromatic hydrocarbons (PAHs) and organochlorine compounds in the breast fat of 44 breast cancer patients and 33 healthy women, showed there were no significant differences in residue levels of PAH, DDT, PCBs, and hexachlorobenzene (HCB) between the two groups. A trend however indicated higher levels of p,p'-DDT, p,p'-DDE and PCBs in the

cancer patients. There were also significantly higher residues of B-hexachlorocyclohexane (the principal metabolite of the organochlorine insecticide lindane) in the samples taken from breast cancer patients (P=0.026). When the data were adjusted for parity and age, the odds ratio in women whose breast fat contained more than 0.1 mg B-HCH/kg fat, was 10.51 with a 95% confidence interval of 2.0-55.26, indicating very significant results. The authors commented that the differences found in the study may have been partially a result of dietary differences between the two groups examined.

In 1992, Falck et al.[41] reported significantly higher levels of PCBs and DDE in mammary adipose tissue taken from 20 women with malignancies compared to 20 women with benign breast disease. Levels of p,p'-DDT were also elevated among cases, but were not statistically significant.

Wolff et al.[4] continued this research and published further results in 1993 (Wolfe et al., 1993). This blind study examined stored blood samples of 14,290 women enroled between 1985 and 1991 in the New York University Women's Health Study. Cohort members who developed breast cancer were included as case patients in this nested case-control study and were compared to women in the study population who did not develop the disease. Adjustments were made for possible confounding factors including age at menarche, age at first birth, body mass index (kg/m^2), months of lactation, first degree family history of breast cancer and of benign breast disease, history of smoking, alcohol consumption and race. Only covariates that altered the regression coefficients of the variables by at least 15% were included in the final model.

The results showed mean levels of DDE and PCBs were higher for the 58 cases compared to the 171 matched controls, but this difference was only statistically significant for DDE. DDE concentrations were approximately 35% higher in patients than in controls, while PCB levels were 15% higher. When examined as a continuous risk factor, there was a 9% increase in the adjusted odds ratio (OR) for breast cancer per unit increase in DDE. This corresponded to a four-fold risk for an elevation of serum DDE from 2.0 to 19.1 ng/ml.

There was no significant difference in PCB concentration between the patients and the controls. When both PCBs and DDE were included in the model, DDE remained virtually unchanged, while the coefficient for PCBs was further reduced in statistical significance.

If adjustments for lactation had not been made in the Wolff study, the results would not have been significant[42]. Lactation has not consistently been associated with a lower risk for breast cancer. Also, because of the limited follow-up time (1-6 months from entry into the study), most of the case patients probably had breast cancer at the time of the sampling, therefore an effect of disease on DDE levels cannot be excluded. The researchers also failed to adjust the data to account for serum lipid content which may have affected the results.

Dewailly et al.[2] reported preliminary results showing significantly higher plasma concentrations of hexachlorobenzene in the plasma of 20 women with malignancies compared to 17 with benign breast tumours. When the case patients were subdivided into groups according to estrogen receptor status, the results proved more interesting. The mean adipose concentrations of organochlorines in the ER-negative case patients were generally lower than those in the control subjects. In the ER-positive patients however, mean fat concentrations of DDE and PCB congener 99 were significantly higher than those in the control subjects. Similar differences were observed when plasma concentrations of DDE were compared (3.5 ug/L in control subjects versus 8.5 ug/L in ER-positive case patients. A relative risk of 8.9 was calculated for the cases compared to the controls. These results suggest that women with hormone-responsive breast cancer, have a higher body burden of DDE than women with benign breast disease, and appears to support the hypothesis that exposure to estrogenic organochlorines may affect the incidence of hormone-responsive breast cancer. The results do not however establish a causal relationship.

In April of this year, Kreiger et al.[1] published the results of the Kaiser study in which blood samples drawn and frozen during routine physical examinations of thousands of women during the late 1960s, were analyzed. Samples taken from 150 women (50 Asian, 50 black and 50 white) who had developed breast cancer an average of 14 years later were matched with 150 controls. No association was found between serum DDT and PCB levels and risk of breast cancer. The results of this study are more convincing than the Wolff study because the sample size is larger, it is a true prospective study with an average period of 14 years

from the time of sampling to development of the disease compared with the very short 1-6 month period in the Wolff study, and the samples were taken prior to the 1972 ban on DDT when women were exposed to much higher residue levels than they are today. It is also noteworthy that these observations contrast sharply with those reported by Dewailly et al.[3] in which the authors noted a significantly higher concentration of DDE in the serum of women with estrogen receptor positive breast cancer. The blood samples in this study contained DDE levels four times greater than those in the Wolff study, and yet no association was found.

Discussion

If DDT exposure is a risk factor in breast cancer, it would be further supported if a plausible mechanism could be advanced. While o,p'-DDT has estrogenic activity, only p,p'-DDE was estimated in the Wolff and Dewailly studies. p,p'-DDE has a very weak estrogenic effect, if any, as measured by receptor binding, however, there are other mechanisms that are capable of producing estrogenic responses.

Organochlorines are known inducers of the cytochrome P-450s in humans[43], and recent evidence suggests they may alter the metabolism of estradiol to produce metabolites with prolonged estrogenic activity[44]. There is also evidence of an inverse relationship in humans between levels of DDE in breast milk and subsequent duration of lactation, suggesting an effect on the endocrine balance[45].

During the metabolism of estradiol in humans, 17B-estradiol is converted to estrone which is then metabolized via two primary pathways. The 2-hydroxylation pathway produces weak estrogens such as 2-hydroxyestrone, while in the second pathway, 16-alpha-hydroxylase produces 16-alpha-hydroxyestrone, which has estrogenic activity equal to that of estradiol[46]. 16-alpha-hydroxyestrone may contribute to breast cancer incidence since women with the disease have a 50% increase in 16-alpha-hydroxylation compared to controls, and its presence could prolong the estrogenic effects of estradiol[44]. Increased 16-alpha-hydroxylase activity in mice has been associated with the development of mammary tumours. Treatment of cells with (200 ng/ml) of 16-alpha-hydroxyestrone resulted in increased DNA repair synthesis proliferative activity compared to the controls ($p<.001$)[17]. It also has minimal binding affinity to sex hormone binding globulins in the blood, which ensures its release into tissues. 16-alpha-hydroxyestrone binds two different ways to estrogen receptors - a covalent bond, forming adducts, and a classical noncovalent interaction similar to that of estradiol[47].

Bradlow[48] has been studying the effect of polycyclic aromatic hydrocarbons and various pesticides on the metabolic pathway that converts estradiol to 16-alpha-hydroxyestrone. If these chemicals, including o,p'-DDT, DDE, kepone and atrazine, enhance this pathway producing higher levels of this metabolite as Bradlow claims, this could suggest an association between these compounds and breast cancer. Critical to this hypothesis however, is the selection of controls. One important criterion for determining the significance of a possible enhancement of the 16-alpha-hydroxylation pathway by these chemicals, is the specificity of the phenomenon. If many unrelated substances induce this pathway, the conclusions may be different.

Conclusion

The etiology of breast cancer is not fully understood although it is widely acknowledged that estrogen levels in the body play a major role. Consequently, compounds that have estrogenic activity or that affect the metabolism of estrogen in such a way as to elevate internal levels, may increase risk of disease. Contemporary human exposures to residues of DDT and other organochlorines are very limited, and therefore this source of exposure seems biologically insignificant compared to other exogenous sources such as oral contraceptives, estrogen replacement regimes and phytoestrogens in food. Many foods commonly consumed contain very high levels of estrogen. For example, cabbage contains 2,400 ng estrogen/3.5 oz serving[49]. It is possible that consumption of foods high in estrogen may contribute more to the risk of developing breast cancer than exposure to estrogenic compounds, such as organochlorine pesticides.

The facts remain however, that breast cancer incidence has been increasing over the past 20 years; the number of estrogen responsive tumours is increasing, particularly among older women who could be carrying a greater body burden of organochlorines than younger women. Since the latency period for some cancers is as long as 20 years, it is possible that the increased number of breast cancers seen in the 1980s and early 1990s were caused by a major environmental contaminant present

in the 1960s, although other plausible explanations cannot be ruled out. If exposure to DDT is an important risk factor, one would expect to see a decline in breast cancer incidence in countries where its use has declined or ceased. In developing countries where DDT is still used, this trend may not be noted.

While it is biologically plausible that DDT exposure could be a minor risk factor for breast cancer, the evidence is not compelling. Reviews by IARC, and the largest prospective study conducted to date do not support an association. Since there are few epidemiological studies of sufficient sample size and adequate protocol to draw a definitive conclusion, further research should be conducted to more fully evaluate the role of xenoestrogens as a risk factor in the development of human breast cancer. □

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REFERENCES

1. Kreiger N, Wolff MS, Hiatt RA, Rivera M, Vogelman J, Orentreich N. Breast Cancer and Serum Organochlorines: a Prospective Study Among White, Black and Asian Women. *J Natl Cancer Inst* 1994; 86(8): 589-599.
2. Dewailly E, Dodin S, Verreault R, Ayotte P, Sauve L, Morin J, Brisson J. High Organochlorine Burden in Women with Estrogen Receptor-Positive Breast Cancer. *J Natl Cancer Inst* 1994; 86(3): 232-234.
3. Davis DL, Bradlow HL, Wolff M, Woodruff T, Hoel DG, Anton-Culver H. Medical Hypothesis: Xenoestrogens As Preventable Causes of Breast Cancer. *Environ Health Perspect* 1993; 101: 372-377.
4. Wolff MS, Toniolo PG, Lee EW, Rivera MK, Dubin N. Blood Levels of Organochlorine Residues and Risk of Breast Cancer. *J Natl Cancer Inst* 1993; 85(8): 648-652.
5. Feuer EJ, Wun L-M, Boring CC, Flanders WD, Timmel MJ, Tong T. The Lifetime Risk of Developing Breast Cancer. *J Natl Cancer Inst* 1993; 85(11): 892-896.
6. Pollner F. A Holistic Approach to Breast Cancer Research. *Environ Health Perspect* 1993; 101(2): 116-120.
7. Canadian Centre for Health Information, Statistics Canada. Obtained from the Cancer Information Service, 755 Concession St., Hamilton, Ontario. 1-800-263-6750.
8. Newman PA. Breast Cancer Incidence is on the Rise - But Why? (News Report). *J Natl Cancer Inst* 1990; 82(12): 998-1000.
9. Glass AG, Hoover RN. Rising Incidence of Breast Cancer: Relationship to Stage and Receptor Status. *J Natl Cancer Inst* 1990; 82(8): 693-696.
10. Harris JR, Lippman ME, Veronesi U, Willet W. Breast Cancer - First of Three Parts. *N Engl J Med* 1992; 327(5): 319-328.
11. Fox SI. *Human Physiology*. W. C. Brow Publishers, 1984, pg.655.
12. Guyton A. Female physiology before pregnancy and the female hormones, in: *Textbook of Medical Physiology* 8th Edition, Philadelphia PA: W. B. Saunders Company, 1991, pp.899-914.
13. Dupont WD, Page DL. Risk Factors for Breast Cancer in Women with Proliferative Breast Disease. *N Engl J Med* 1985; 312: 146-151.
14. Bradley CJ, Kledzik GS, Meites J. Prolactin and Estrogen Dependency of Rat Mammary Cancers in Early and Late Stages of Development. *Cancer Res* 1976; 36: 319-324.
15. Soto AM, Sonnenschein C. The Role of Estrogen in the Proliferation of Human Breast Tumour Cells (MCF-7). *J steroid Biochem* 1985; 23: 87-94.
16. Kay TIA, Pike MC. The Role of Oestrogens and Progestagens in the Epidemiology and Prevention of Breast Cancer. *Eur J Cancer Clin Oncol* 1988; 24(1): 29-43.
17. Tsieng NT, Suto A, Wong GY, Osborne MP, Bradlow HL. Induction by Estrogen Metabolite 16-alpha-Hydroxyestrone of Genotoxic Damage and Aberrant Proliferation in Mouse Mammary Epithelial Cells. *J Natl Cancer Inst* 1992; 84 (8): 634-638.
18. Henderson BE, Ross RK, Pike MC. Hormonal Chemoprevention of Cancer in Women. *Science* 1993; 259: 633-638.
19. Pike MC, Henderson BE, Krailo MD et al. Breast Cancer in Young Women and Use of Oral Contraceptives: Possible Modifying Effect of Formulation and Age of Use. *Lancet* 1983; 2: 926-930.
20. Miller DR, Rosenberg L, Kaufman DW, Stolley P, Warshauer ME, Shapiro S. Breast Cancer Before Age 45 and Oral Contraceptive Use: new findings. *Am J Epidemiol* 1989; 129: 269-280.
21. Romieu I, Willet WC, Colditz GA. Prospective Study of Oral Contraceptive Use and the Risk of Breast Cancer in Women. *J Natl Cancer Inst* 1989; 81: 1313-1321.
22. Thomas DB. Oral Contraceptives and Breast Cancer (Commentary). *J Natl Cancer Inst* 1993; 85 (5): 359-363.
23. Colditz GA, Stampfer MJ, Willett WC, Hennekens CH, Rosner B, Speizer FE. Prospective Study of Estrogen Replacement Therapy and Risk of Breast Cancer in Postmenopausal Women. *JAMA* 1990; 264: 2648-2653.
24. Henrich JB. The Postmenopausal Estrogen/Breast Cancer Controversy. *JAMA* 1992; 268(14): 1900-1902.

25. Nachtigall MJ, Smilea SW, Nachtigall RD, Nachtigall RH. Nachtigall, LE. Incidence of Breast Cancer in a 22-Year Study of Women Receiving Estrogen-Progestin Replacement Therapy. *Obstet Gynecol* 1992; 80(5): 827-830.

26. Colditz GA. Hormone Replacement Therapy and Risk of Breast Cancer: Results from Epidemiologic Studies. *Am J Obstet Gynecol* 1993b; 168(5): 1473-1479.

27. Boice JD Jr., Monson RR. Breast Cancer in Women After Repeated Fluoroscopic Examinations of the Chest. *J Natl Cancer Inst* 1977; 59: 823-832.

28. McGregor H, Land CE, Choi K. Breast Cancer Incidence Among Atomic Bomb Survivors, Hiroshima and Nagasaki, 1950-1969. *J Natl Cancer Inst* 1977; 59: 799-811.

29. Willet W. The Search for the Causes of Breast and Colon Cancer. *Nature* 1989; 338: 389-394.

30. Ballard-Barbash R, Schatzkin A, Carter CL, Kannel, WB, Kreiger, BE, D'Agostino RB, Splansky, GL, Anderson, KM, Heinel WE. Body Fat Distribution and Breast Cancer in the Framingham Study. *J Natl Cancer Inst* 1990; 82(4): 286-290.

31. Howe GR, Hirohata T, Hislop TG, Iscovich JM, Yuan JM, Katsouyanni K, Lubin F, Marubini E, Modan B, Rohan T, Toniolo P, Shunzhang Y. Dietary Factors and Risk of Breast Cancer: Combined Analysis of 12 Case-Control Studies. *J Natl Cancer Inst* 1990; 82(7): 561-569.

32. Boyd N. Nutrition and Breast Cancer. *J Natl Cancer Inst* 1993; 85 (1): 6-7.

33. Colditz GA. Epidemiology of Breast Cancer - Findings from the Nurses' Health Study. *Cancer Supplement* 1993a; 71(4): 1480-1489.

34. Mansfield CM. A Review of the Etiology of Breast Cancer. *J Natl Med Assoc* 1993; 85(3): 217-221.

35. Byers T, Graham S, Rzepka T, Marshall J. Lactation and Breast Cancer: Evidence for a Negative Association in Pre-Menopausal Women. *Am J Epidemiol* 1985; 121: 664-674.

36. McTiernan A, Thomas DB. Evidence for a Protective Effect of Lactation on Risk of Breast Cancer in Young Women: Results from a Case-Control Study. *Am J Epidemiol* 1986; 124: 353-358.

37. London SJ, Colditz GA, Stampfer, MJ et al. Lactation and Risk of Breast Cancer in a Cohort of U.S. Women. *Am J Epidemiol* 1990;132: 17-26

38. Bradlow L. Personal communication, November 16, 1993.

39. Nelson JA. Effects of Dichlorodiphenyltrichloroethane (DDT) and Polychlorinated Biphenyls (PBC) Mixtures on 17B-Estradiol Binding to Rat Uterine Receptor. *Biochem Pharmacol* 1974; 23: 447-451.

40. Forster MS, Wilder EL, Heinrichs WL. Estrogenic Behavior of 2-(o-chlorophenyl)-2-(p-chlorophenyl)-1,1,1-trichloroethane and its Homologues. *Biochem Pharmacol* 1975; 24: 1777-1780.

41. Kupfer D, Bulger WH. Studies on the Mechanism of Estrogen Actions of o,p'-DDT: Interactions with the Estrogen Receptor. *Pest Biochem Physiol* 1976a; 6: 561-570.

42. Mason RR. Schulte GJ. Interaction of o,p'-DDT with the Estrogen-Binding Protein (ESP) of DMBA-Induced Rat Mammary Tumors. *Res Commun Chem Pathol Pharmacol* 1981; 33(1): 120-127.

43. Kupfer D, Bulger WH. Metabolic Activation of Pesticides with Proestrogenic Activity. *Fed Proc* 1987; 46(5): 1864-1869.

44. Robison AK, Mukku VR, Spalding DM, Stancel GM. The Estrogenic Activity of DDT: The In Vitro Induction of an Estrogen-Inducible Protein by o,p'-DDT. *Toxicology and Applied Pharmacology* 1984; 76: 537-543.

45. Nelson JA, Struck, RF, James R. Estrogenic Activities of Chlorinated Hydrocarbons. *J Toxicol Environ Health* 1978; 4: 325-339.

46. Kupfer D, Bulger WH. Interactions of Chlorinated Hydrocarbons with Steriod Hormones. *Fed Proc* 1976b 35: 2603-2608.

47. Kupfer D. Effects of Pesticides and Related Compounds on Steroid Metabolism and Function. *Crit Rev Tox* 1975; 4: 83-124.

48. Ireland JS, Mukku VR, Robison AK, Stancel GM. Stimulation of Uterine deoxyribonucleic acid synthesis by 1,1,1-trichloro-2-(p-chlorophenyl)-2-(o-chlorophenyl)-ethane(o,p'-DDT). *Biochem Pharmacol* 1980; 29: 1469-1474.

49. Robison AK, Sirmaks DA, Stancel GM. DDT Supports the Growth of an Estrogen-Responsive Tumor. *Toxicol Lett* 1985b; 27: 109-113.

50. Bulger WH, Kupfer D. Estrogenic Action of DDT Analogs. *Am J Ind Med* 1983; 4: 163-173.

51. Kupfer D, Bulger WH. Estrogenic Properties of DDT and its Analogs, in: Estrogens in the Environment", J.A. McLaughlin Editor, Elsevier/North Holland New York, 1980, pp.239-263.

52. Bitman J, Cecil HC, Harris SJ, Fell VJ. Estrogenic Activity of o,p'-DDT Metabolites and Related Compounds. *J Agric Food Chem* 1978; 26: (1): 149-151.

53. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, 1991. Volume 53, Occupational Exposures in Insecticide Application and Some Pesticides. International Agency for Research on Cancer (IARC), World Health Organization.

54. Cabral JRP. DDT; Laboratory Evidence, in: *IARC Scientific Publications*, 1985, 65: 101-105.

55. Higginson J. DDT, Epidemiological Evidence, in: *IARC Scientific Publications*, 1985, 65: 107-117.

56. Wasserman M, Nogueira DP, Tomatis L, Mirra AP, Shibata H, Arie G, Cucos DS. Organochlorine Compounds in Neoplastic and Adjacent Apparently Normal Breast Tissue. *Bull Environ Contam Toxicol* 1976; 15: 478-484.

57. Unger M, Klaer H, Blichert-Toft M, Olsen J, Clausen J. Organochlorine Compounds in Human Breast Fat from Deceased with and Without Breast Cancer and in a Biopsy Material from Newly Diagnosed Patients Undergoing Breast Surgery. *Environmental Research* 1984; 34: 24-28.

58. Austin H, Keil JE, Cole P. A Prospective Follow-Up Study of Cancer Mortality in Relation to Serum DDT. *Am J Public Health* 1989; 79(1): 43-46.

59. Westin JB, Richter E. The Israeli Breast-Cancer Anomaly. *Ann N Y Acad Sci* 1990; 609: 269-279.

60. Mussalo-Rauhamaa HM, Hasanen E, Pyysalo H, Antervo K, Kauppila R, Pantzar P. Occurrence of Beta-hexachlorocyclohexane in Breast Cancer Patients. *Cancer* 1990; 66(10): 2124-2128.

61. Falck F, Ricci A, Wolff M, Godbold J, Deckers P. Pesticides and Polychlorinated Biphenyl Residues in Human Breast Lipids and Their Relation to Breast Cancer. *Archives of Environmental Health* 1992; 47(2): 143-146.

62. Longnecker MP, London SJ. Re: Blood Levels of Organochlorine Residues and Risk of Breast Cancer - Correspondence. *J Natl Cancer Inst* 1993; 85(20): 1696-1697.

63. Alvares AP, Fischbein A, Anderson KE, Kappas A. Alterations in Drug Metabolism in Workers Exposed to Polychlorinated Biphenyls. *Clin Pharmacol Ther* 1977; 22(2): 140-145.

64. Schneider J, Kinne D, Fracchia A, Pierce V, Anderson KE, Bradlow HL, Fishman J. Abnormal Oxidative Metabolism of Estradiol in Women with Breast Cancer. *Proc Natl Acad Sci USA* 1982; 79: 3047-3051.

65. Rogan WJ, Gladen BC, McKinney JD et. al. Polychlorinated Biphenyls (PCBs) and Dichlorodiphenyl dichloroethane (DDE) in Human Milk: Effects on Growth, Morbidity and Duration of Lactation. *Am J Public Health* 1987; 77: 1294-1297.

66. Longcope C. Relationships of Estrogen to Breast Cancer, of Diet to Breast Cancer, and of Diet to Estradiol Metabolism (Editorial). *J Natl Cancer Inst* 1990; 82(11): 896-897.

67. Swaneck GE, Fishman J. Covalent Binding of the Endogenous Estrogen 16-Alpha-Hydroxyestrone to Estradiol Receptor in Human Breast Cancer Cells. Characterization and Intranuclear Localization. *Proc Natl Acad Sci USA*. 1988; 85: 7831-7835.

68. Vines G. Pesticides Linked to Breast Cancer (News Report). *New Scientist*, 1993, Sept 25 pp. 4.

69. Verdeal K, Ryan DS. Naturally Occurring Estrogens in Plant Foodstuffs - a Review. *J. Food Prot* 1979; 43: 577-583

DISEASE CONTROL SERVICE COMMENT

Breast cancer incidence rates have been increasing among Ontario women. There were 5760 new cases of breast cancer diagnosed in Ontario women in 1991 compared to 3714 new cases diagnosed in 1981, a 55% increase over the ten year interval. Similarly, there was a 28% increase in breast cancer mortality between 1981 (1395 deaths) and 1991 (1785 deaths) and 84% of these deaths occurred among women aged 50 years and over. With an aging population, breast cancer will continue to contribute significantly to the morbidity and mortality burdens for Ontario women. Breast cancer is clearly an important target for public health intervention, other than promotion of screening, should preventable causal linkages be defined.

Ontario residents are concerned as mounting evidence continues to reinforce a possible relationship between exposure to persistent toxic substances in the environment and a variety of diseases, including breast cancer. As indicated in the article, the causes of breast cancer are not fully understood. With known risk factors accounting for only 30% of cases, researchers have focused on environmental carcinogens which could account for the remaining 70%. This extensive literature review presents an analysis of up to date scientific research which has examined possible causal linkages between organochlorine residues and breast cancer.

The role of estrogen in the development of breast cancer has lead researchers to examine possible association between breast cancer and DDT (and its metabolite DDE) which have estrogenic activity. Although it is biologically plausible that these persistent toxic agents could be risk factors for breast cancer, the results are not compelling. Most of the studies have suffered from poor design, inadequate methodology and insufficient sample size which have limited the interpretation of their results. The article mentions that a review by the International Agency for Research on Cancer (IARC) and the largest prospective study have not found an association between DDT and breast cancer.

Levels of DDT in environmental media in Ontario have been decreasing since Canada banned its use. However, since DDT is still manufactured elsewhere and used in many developing countries, elevations in DDT levels may be noticed as the agent cycles through water and air. Breastfeeding is the main pathway for exposure of Ontario infants to organochlorines. Breastfeeding for one year provides a child with a large proportion of its lifetime exposure.

By imposing limitations on fish consumption where organochlorine levels exceed guidelines, Ontario has attempted to limit the exposure of its population to DDT and other organochlorines. Some areas have been closed to commercial fishing and advisories are in place to limit consumption of certain sport fish.

Additional action to reduce exposure by further limiting food consumption (fish and breast milk) must be weighed against the benefits of protection against disease, such as cardiovascular disease, and a healthy population of children. Articles, such as this literature review, present opportunities to update knowledge to assist in guiding choices for public health action. ❑

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