FOOD SAFETY ISSUES

HEARINGS

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE

OF THE

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SECOND SESSION

FEBRUARY 19, 1992

MINOR-USE PESTICIDES, INTEGRATED PEST MANAGEMENT, AND BIOLOGICAL PESTICIDES

FEBRUARY 26, 1992

RISK ASSESSMENT FOR ESTABLISHING PESTICIDE RESIDUE TOLERANCE

MARCH 4, 1992

PREEMPTION OF LOCAL AUTHORITY UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

MARCH 11, 1992

USDA PESTICIDE PROGRAMS

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MARCH 11, 1992

USDA PESTICIDE PROGRAMS

WITNESSES

Mr. ROSE. Our first panel is one person. If you read his testimony, he covers the subject that we're discussing today in 32 single-spaced pages, which we are happy to put into the record in its entirety and hope and pray that you will summarize for us. [Laughter.]

We are very glad to have Charles M. Benbrook, who is a consultant with Benbrook Consulting Service in Dickerson, MD. He knows a great deal about this subject.

We're glad to have you, sir.

STATEMENT OF CHARLES M. BENBROOK, CONSULTANT, BENBROOK CONSULTING SERVICES

Mr. BENBROOK. Thank you.

As Mr. Brown and Mr. Roberts remember, it has been a long and eventful decade dealing with pesticide issues within this subcommittee. Even in 32 single-spaced pages, it was possible only to hit a few of the high points of the debate.

I would like to begin by complimenting you, Mr. Chairman, for drafting H.R. 3742. It is a solid and thoughtful bill and a good point of departure for the subcommittee's efforts. Clearly, the time has come and there is a consensus that some changes are needed in the suspension and cancellation language. I think H.R. 3742 is pretty close to the kind of language that everyone can agree to.

Also, obviously the Congress is going to have to deal with the food safety problems that have come to be known as "Delaney's paradox." Mr. Chairman, I believe the language you have in H.R. 3742 is very close to the kind of consensus compromise position that is both scientifically defensible and also palatable to all of the major constituencies.

I do address in my testimony and direct your attention when you have your hearing on risk assessment to some of the details of how EPA is directed to measure consumption and measure exposure to pesticides in the process of establishing tolerances at a so-called negligible-risk level. Some of the fine print that has not received a great deal of attention will have a profound impact on the ability, for example, of registrants to defend minor uses.

I point out several examples and places in the risk assessment process that really warrant the attention of this subcommittee in the nature of assuring that you don't build into the statute another major hurdle for minor uses to get over. I only alert you to that so that during your risk assessment hearing you can focus on those issues.

I also hope and urge the subcommittee to use and build on some of the excellent ideas that the witnesses appearing later today are bringing forth on ways to accelerate the rate at which so-called biorational, or biocontrol, agents can get registered.

We have a serious problem in many of our specialty crops with a number of pests. We are down to just one or two effective products. In many cases, these products are beginning to not work very well because of genetic resistance and other factors. It's really critical that the U.S. farmer begin to gain access to a lot of the innovative chemistry and these newer products that have been used in other countries in some cases for several years.

So I hope that you will take some of the ideas that are brought forth and incorporate them into an expanded minor-use title and a safer pesticide title in H.R. 3742.

I know that Mr. Brown and Mr. Roberts would love to find a——

Mr. ROSE. Let me interrupt you and ask you to tell us where the better pesticides in other countries are coming from. In other words, what are the major countries that have done a better job on some of these minor-use problems, but because of reregistration expenses are not here?

Mr. BENBROOK. Pat Weddle, who is going to be on the next panel, has a really compelling example to share with you involving pear IPM systems in the Po River Valley in Italy.

A lot of the new chemicals—the pheromone-based technologies, the insect growth regulators—these chemicals have often been developed in Agriculture Research Service/USDA laboratories. A lot of the new science that lies behind some of these innovative approaches to pest management have been developed in the United States, both in the public and private sector. But for a host of reasons, it has proven very difficult to get these novel products through the regulatory process and to get them worked into the kind of education programs that are used to deliver technology to farmers.

It is ironic that in this country that has invested so much in understanding the science of safe pest control, that we really have not done a very good job in utilizing and commercializing these systems to benefit our own farmers. It is a very important challenge to change this shortcoming.

I would just like to close by urging the subcommittee, as you complete action on H.R. 3742, to not allow this debate about negligible risk and this ambiguity about what the law is to go on much longer. The inconsistency in the FIFRA statute and the Food, Drug, and Cosmetic Act has been a recognized problem for almost a decade now. Virtually everyone is on record as saying that it must be resolved. It is a task that only the Congress can do because this is a fundamental statutory conflict.

I really would urge the subcommittee to move ahead and do whatever you feel you must to reach a compromise with the provisions in H.R. 3742, but do something. It is much better to resolve this issue, get a set of laws and regulatory policies that EPA can implement, and start making these decisions and getting on with it. If that is not done, there is another wave of data coming in, another wave of Alars that are just waiting to happen. If the laws aren't reformed so that EPA can make reasoned and expeditious decisions, it's going to prove a very negative and frustrating decade indeed.

I would like to close there. I hope that you will have some time—especially some of the new members of the subcommittee that haven't been through the development of this issue over the last decade—to read the statement. I would be glad to answer any questions you may have for me, Mr. Chairman.

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

Mr. ROSE. Thank you, sir.

Are there questions by members of the subcommittee?

Mr. Brown.

Mr. BROWN. Mr. Chairman, I don't have a question, but I want to reiterate what Dr. Benbrook just said with regard to some of the new members of the committee.

Chuck was the staff director for this subcommittee in the period that he indicates in his testimony and went from there to serve as the Staff Director of the Food and Agriculture Group of the National Academy of Sciences. But while he was working for this subcommittee, he began the process which we are continuing today. He conducted some of the most exhaustive research in this area and helped us to focus national attention on it.

So I think it's important that all the members of the subcommittee be aware of that background and his statement, that does include a very good historical review of it.

In addition to that, of course, he has the best advice for the chairman of this subcommittee that I have ever seen on the first page of his testimony in the quotation from Churchill in which he says, "A good measure of character is one's ability to go from failure to failure without a loss of enthusiasm." Mr. Chairman, I hope you will not lose your enthusiasm. [Laughter.]

Mr. ROSE. You noticed that I shared that with Leon Panetta before he left. He thought he could use that quotation.

Mr. ROBERTS. Would the gentleman yield?

Mr. ROSE. Mr. Roberts.

Mr. ROBERTS. I thank the Chair for yielding and would like to associate myself with the remarks of the gentleman, Sir Winston Brown, from California and England, the New Great Britain. [Laughter.]

But at any rate, I want to say on behalf of Chuck and to advise the new members—have we been doing this that long that we have to do this kind of thing? It's been longer than that.

Chuck is a very valuable resource and probably knows more about this from a staff consideration than anybody else. He has always attempted to shine the light of truth into darkness. There were times that I had to help you with the flashlight, and there were some areas where we wanted to poke that maybe you didn't want to poke and vice versa. But with that caveat, I would urge all members to take advantage of Chuck's knowledge and further observations.

Mr. ROSE. Any other comments or questions?

Mr. Stenholm.

Mr. STENHOLM. On page 3 you make a statement in your written testimony that I would like you to go a little further on. I quote you in saying, "I hope that the environmental community, particularly individuals committed to activism and determined to make things change, will come to accept that farmers are their best and most important allies in efforts to reduce pesticide use and related hazards."

Could you go a little further on that as to some of the things that this committee might consider in seeing that that truth is better accepted?

Mr. BENBROOK. I think that one way is by highlighting the importance of this hearing and raising the visibility and attention directed to what is going on at the farm level and what is needed to

accelerate the adoption of IPM. We need to highlight the need for regulatory reforms to bring the new chemistry on line quicker.

One of the things that I feel is very important about this goal is that it is a challenge the environmental community can embrace. Over the last decade—as all of you know—environmentalists have had a lot of criticisms, made a lot of allegations about how unsafe the food supply is, and have been very provocative in criticizing American agriculture's reliance on conventional pesticide technologies.

They have done a service in bringing to the attention of the Congress and the country some of the problems with pesticides. But the environmental community has been lax, in my judgment, in coming forward with positive, constructive alternatives and ways to deal with problems that everybody agrees exist. So I think that what I would urge the subcommittee to do is ask the environmental community, in the context of developing a safer pesticide policy, what sort of ideas could they get behind. What kind of initiatives, in concert with farm groups and crop protection specialists, might they support?

I think there is a lot of room for agreement and progress.

Mr. STENHOLM. How do we best handle the individuals or groups that can accept no pesticides, no man-made help in their proposals? They honestly and sincerely believe that we can eliminate the chemical industry. How do we handle them? These individuals or groups absolutely contribute to the destruction of farmers and ranchers on a regular basis, when they in fact make these assertions and then they are believed?

Mr. BENBROOK. They get their day in court, obviously. There have been many people who have come before this body over the last 10 years that have advocated extremely aggressive regulatory initiatives and have advocated zero risk.

But Congressman, I think that we have to understand that there are two sides to this debate. The sides have kind of become more and more polarized. They have taken more and more extreme positions. They have done it because they have felt it's the only way to advance their cause.

I don't think there are very many responsible environmentalists that either believe it is feasible or necessary to totally eliminate pesticide use. I think there are some people that make that argument in the heat of debate, but I don't think there's a great deal of credibility in that position, particularly in the last few years. I think people are coming to understand that we have to control pests. The capacity to do that has a profound impact on the quality and cost of our food supply.

I don't think that there is a great deal of credibility in just saying, "Let's eliminate all pesticides," but I do think that those people are going to continue to challenge the EPA, State regulatory agencies, and this body, to show some progress toward safer crop protection. It is the absence of that progress that continues to give those people a forum.

That's why I urge the subcommittee to try to get some of these long-standing issues resolved in a credible way so that the system can move forward. I think that's what will tone down the rhetoric and everybody can get behind taking a step this year and another

step next year. But until that process gets underway, I think the extremists will continue to contribute to a shrillness in the debate and make your jobs much harder.

Mr. ROSE. Any other comments?

Thank you, sir.

Mr. BENBROOK. Thank you, Mr. Chairman.

Mr. ROSE. We next have a panel of four people, Hon. Rusty Areias, the chairman of the committee on Agriculture of the California Assembly in Sacramento, CA; Mr. James W. Wells, the director of the department of pesticide regulation, California Environmental Protection Agency, Sacramento; Mr. Patrick W. Weddle, president, Weddle, Hansen, and Associates, Placerville, CA; and Mr. Larry Elworth, director, apple marketing program, Pennsylvania Apple Marketing Board, Pennsylvania Department of Agriculture, Harrisburg, PA.

Gentlemen, we are glad to have you. Mr. Areias, we already had you introduced to us, and we are honored that you are here, sir. Thank you for being with us.

When new Members of Congress come from the California State Assembly, they always come up to my Committee on House Administration and say, "Why don't you run Congress like the California State Assembly?" When we find out some of the help that you all get in running your assembly, we are very jealous and maybe you can help us work on that some day. [Laughter.]

We are delighted to have you and look forward to your comments.

STATEMENT OF RUSTY AREIAS, CHAIRMAN, COMMITTEE ON AGRICULTURE, CALIFORNIA ASSEMBLY, STATE OF CALIFORNIA

Mr. AREIAS. Thank you very much, Mr. Chairman and members of the subcommittee.

My name is Rusty Areias and I am a dairyman from Los Banos, CA, on the western edge of the great San Joaquin Valley. On my dairy, which was started by my immigrant grandfather, we milk over 2,000 cattle every day and we grow the feed for those cows on 3,600 acres of farmland.

In addition to being an agriculturist, I am a member of the California State Assembly and I am currently the chairman of the assembly committee on agriculture.

It is indeed an honor to be invited to testify before this important policy committee of the Congress. I represent a farming district, as you do, Mr. Chairman, and I share your pride in the accomplishments of American agriculture. We are part of a farming culture so productive that the average American has earned enough to feed his or her family by 11 a.m. on Monday morning of the workweek, a farm economy so efficient that less than 5 percent of the people can grow the food and fiber for the rest of the society, and still have enough left over to feed millions of people overseas, including our new friends in the Commonwealth of Nations.

We have a great story to tell. In California, we produce over 250 commercial agricultural commodities. In several of those commodities—including almonds, raisins, artichokes, and prunes—California's production represents 100 percent of the Nation's production.

We do not have a commercial peanut industry, Mr. Chairman, but overall California leads the Nation in agricultural revenues and in the value of our exports to other nations.

Now I am a practicing farmer, but I'm also in politics and I have to answer many of the same tough questions that those of you sitting on the dais have had to confront—questions about Government subsidies, about wages and working conditions to farmworkers, about water use, about agriculture's use of pesticides, herbicides, fungicides, and fertilizers. While these are tough questions, they are not always asked maliciously. Some are questions that we should be asking ourselves both as agriculturalists as well as policymakers.

Let me give you a good example. In California, by general consensus, we have the most aggressive system of regulation of agricultural chemicals in the Nation, and perhaps anywhere in the world. We also have the most highly trained and strictly licensed crop consultants, known as pest control advisers, or PCA's. I would put our system of pest control advisers against any in the Nation. But the truth is that more than half the men and women licensed by the State to give advice on the use of restricted agricultural chemicals are employees of companies whose income depends on the sale of those very same chemicals.

In my estimation, as chairman of the State assembly committee on agriculture, and as a lifetime farmer, the relationship between pest control advisers who are licensed to make professional recommendation and their compensation based upon chemical sales raises questions that we in agriculture should confront before someone else does it for us.

That's why, after working with the industry for over a year, I introduced assembly bill 2786 to prohibit compensation of licensed crop consultants based upon the volume of pesticides that they sell. Most agricultural groups have yet to take a position on my bill, but I predict that in the end the majority of production agriculture will not oppose it, that the bill will pass, and that the Governor will sign it.

Production agriculture has received an enormous boost over the years from the chemical industry. I have used tons of herbicides and pesticides on my ranch. We acknowledge to the good which can be derived from chemistry. New chemical products have produced better yields, which mean lower prices for consumers and more attractive produce, all with an enviable record of safety.

But farmers should rule their own future and make their own decisions about the direction their industry will take. Indeed, most of the farmers I know have decided it's good business to reduce dependence on chemicals. But the transition is slow and right now times are tough. Farmers are being squeezed by overseas competition, by changing standards in the financial industry, by pressures from sprawling urban development, and by threats to withhold the water upon which farming depends.

But even more crucial to the plight of growers in California is our eroding ability to control pests. I need only remind you of the destruction brought on by the sweetpotato whitefly in Imperial and Palo Verde Valleys of California and the futility of combating that pest with any kind of chemical silver bullet.

Many farmers feel that the combined punch of government regulation and manufacturer reluctance to support minor-use products is like a noose tightening around their necks. For example, California's new unified environmental agency, Cal-EPA, under the able leadership of James Strock, a veteran of policy discussions with this subcommittee, recently announced the beginning of suspension proceedings against over 3,000 registered products that are not in compliance with California's pioneering pesticide data gaps law, the Birth Defects Prevention Act of 1984.

You talk about agricultural protection, that in my mind is the best kind of agricultural protection, when you can fill the data gaps so that when your critics come forward about the far-reaching implications of one product or another, you can go in and absolutely defend what the carcinogenic, reproductive, toxicological, or any kind of other far-reaching implications or effects are. That's the kind of agricultural protection we need so that we can defend the products.

What has happened in the last 10 years is that the burden of proof has changed from those who have been critical of the industry, its practices, its products, and its procedures, to those of us who use those products. I think it is clear that the burden of proof is now on us.

California's complex system of regulating agricultural chemicals, in my mind, is the most effective in the Nation. While growers often resist the changes in legislation, it is to their credit that they support the current system and learn to live with the new laws.

Our program in California recently moved from the State agricultural agency to a new unified environmental agency, a move made more tolerable because they had the wisdom to keep Jim Wells, one of the today's panelists, as its director. It has the strictest standards for registering new products and the most elaborate system for actual use of pesticides.

We do more residue testing than the Federal Government. As mentioned earlier, we have the highest standards for licensing crop consultants and pest control advisers. Notwithstanding these benchmarks for pesticide regulation, public confidence continues to erode, as evidenced by the near success of the big green initiative, and by the continuing introduction of punitive legislation seeking further restriction of the chemical tools to which farmers have grown accustomed.

The California State Legislature reflecting the demographic realities of our society, which are overwhelmingly in California urban and suburban, would adopt even more restrictive pesticide laws, were it not for agriculture's shrewd use of procedural strategies, and our ability to build legislative coalitions. But those coalitions are also disintegrating.

I mark the date of the fracture between rural legislators and a handful of their urban colleagues as the day in 1989 when the helicopters were launched over the vast suburbs of Los Angeles to attack the Mediterranean fruit fly. Many legislators until then were willing to support the grower point of view during legislative debates. They suddenly concluded that being tough on farmers was good politics.

The regulatory and political picture for agriculture is grim and we are only 2 years into the decade of the 1990's, the so-called environmental decade. I believe it will be a dreadful decade for farmers in California and around the Nation unless our industry takes charge of its future and accelerates the movement toward a system of crop production and protection based more on our skill and knowledge of natural systems than on our ability to apply greater and greater amounts of chemicals under stricter and stricter rules imposed by a less and less sympathetic majority.

Very much to its credit, the agricultural industry in California leads the Nation in the development and utilization of integrated pest management programs. In recent years, there is evidence of a halt in the annual increase of total pesticide use in California. Indeed, thanks to legislation sponsored by the major farm groups in California, we now have a system of 100 percent pesticide use reporting. This system, while adding an additional burden on the grower and the crop consultant, will establish a credible data base for determining actual patterns of pesticide use, rather than forcing policymakers to rely on sales data or the undocumented claims of some environmental groups.

We are making progress. Growers are learning that IPM is more than just slogan, that it is a matter of survival and it can deliver on the bottom line. But these positive trends need to be encouraged and accelerated. They should be encouraged under the leadership of those who understand and support productive and profitable agricultural enterprises.

Regulatory reforms are needed, Mr. Chairman. H.R. 3742 contains provisions that are a major step in the right direction, to ensure that biologically rational alternatives can be integrated into the product stream as quickly as possible without being subject to the same exhaustive data requirements as their synthetic counterparts.

The minor-use provisions of your bill are also important to us in California because nearly all our crops fall under the definition of minor-use crops. I believe it is imperative that we develop a strategy to keep the greatest diversity of pest control products possible for all commodities. Without an affirmative strategy for minor-use chemicals and the aggressive of biorational alternatives, cancellations could result in the substitution of even more environmentally hostile products and accelerated pest resistance to a narrower range of products.

Substitution of biologically intensive IPM programs for the current chemically intensive regimes will require a more highly trained corps of crop consultants and pest control advisers. In California, we are moving in that direction. I believe my new bill will help and I am pleased to note that the pest control advisers in California, already the most highly trained in the Nation, are considering a number of steps to increase the skill and professionalism of their membership, including the development of new training and examination standards relative to biological control strategies, and the development of a professional peer review process.

Carefully trained PCA's are only as good as the information they can cull from the most current research and research on biology of crop systems is woefully inadequate. Indeed, in California, budget

cuts imposed on the University of California, have dramatically reduced the amount of money available for research into alternative pest control products.

Many growers, through their commodity groups, already fund research into biological, but the amount spent on developing biological control, versus the amount invested by chemical companies on new chemical products is minuscule. To help in a small way, I have introduced legislation this year to appropriate $2 million for an IPM competitive grants program at the University of California, but much more funding is needed.

To remedy this funding shortage, I recommend Congress develop an IPM research program to provide grants to those commodity groups and States which provide private or public matching funds. To fund the Federal share of this effort, I would suggest the Congress impose a small research and education excise tax on the retail sale of agricultural chemicals destined for home use. Some of the funds from such a tax could be used to develop more consumer friendly retail pesticide labels and to ensure that retail sales people are knowledgeable of the safe use of agricultural chemicals.

Finally, let me say that I have been chairman of the State assembly agricultural committee for slightly more than 1 year. I am not too sure how much longer I will be the chairman. In California, many of you have heard that we have term limits that have been imposed, an epidemic that may or may not be spreading across the Nation. But like a lot of things, it started in California. But while I am chairing this policy committee, I intend to use the powers of the committee to make more tools, not less, available to farmers. By far the most dependable tool we can give them is the scientific knowledge they need to practice the art of agriculture.

Over the next several months the assembly committee on agriculture will hold oversight hearings on the same issues that you are examining today, the strategies for moving more rapidly toward a more biologically intensive and knowledge-based system of agricultural crop production and protection. I look forward to sharing the fruits of our work with your committee.

Thank you very much for your attention. I would be happy to answer any questions that you may have.

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

Mr. ROSE. Thank you, Mr. Chairman. We will briefly hear from your other panel members and then we will have questions.

Mr. James Wells, director of the department of pesticide regulations, California Environmental Protection Agency.

Mr. Wells.

STATEMENT OF JAMES W. WELLS, DIRECTOR, DEPARTMENT OF PESTICIDE REGULATION, CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

Mr. WELLS. Mr. Chairman and members of the committee, I am pleased and honored to be here today to discuss issues critical to the future of California agriculture as well as national agriculture.

It has been said that within the decade agriculture will have only half the chemical tools it now uses. A combination of regula-

BRINGING THE FIFRA REFORM DEBATE DOWN TO EARTH

Testimony Presented February 19, 1992 by

Dr. Charles Benbrook
Benbrook Consulting Services[1]

Before the

Subcommittee on Department Operations,
Research and Foreign Agriculture

Committee on Agriculture
U.S. House of Representatives

Mr. Chairman and members of the subcommittee, it is a real honor to present testimony before you today. As Mr. Roberts and a few other members of the subcommittee remember -- indeed wish they could forget -- I had the honor of serving as this subcommittee's staff director from 1981-1983 under the Chairmanship of George Brown. It was an active period for the subcommittee, an era of great change in the nation's regulatory programs and policies.

The issues that dominated the subcommittee's agenda back in the early 1980's remain very much unresolved, despite dozens of hearings, 10 or more serious efforts to draft reform legislation, and unimaginable hours of effort in search of consensus and compromise. Despite the long, disappointing road behind us, it is encouraging to see such enthusiasm and interest among the members of the subcommittee in today's hearing. Churchill once said something that aptly applies to this subcommittee--

A good measure of character is one's ability to go from failure to failure without a loss of enthusiasm.

Looking back Mr. Chairman, I am afraid most people would agree that we collectively have little to show in the way of legislative progress for all the smoke and heat generated by the pesticide wars of the 1980's. We are not much closer to resolving long-standing disagreements about how to balance the public's interest in safe food and a clean environment with the public's interest in an abundant, affordable, and nutritious food supply. And then of course it has always been difficult to deal with the intense

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special interest pressure from pesticide manufacturers and environmental extremists with only an "anti-" agenda.

I commend the subcommittee for shifting the focus of its initial 1992 hearing on pesticide regulatory issues toward how the law and regulatory program activities impact pest control practices on the farm.

In the context of pesticide regulatory policy, there have now been 10 years of debate in this subcommittee and the Congress as a whole on how "safe" must "safe" be, on how to do risk assessments, on the level of negligible risks, and on how to unravel Delaney's Paradox. These debates have been vital but I hate to say they have changed almost nothing in the real world.

These debates have not produced a consensus on what level of risk can be deemed acceptable.

We are just a little closer toward consensus on how to estimate dietary exposure to pesticides -- a key step in the risk assessment process.

The science of toxicology has made great strides, but still we have to live with tremendous uncertainties in predicting the level of human risk that might arise from use of a particular pesticide.

Very few tolerances have been reduced despite a dozen appearances on the Hill in the last few years during which EPA officials have acknowledged that several hundred existing tolerances are well above the so-called negligible risk level proposed by the Administration -- and more to come.

The statutory conflicts between the Food, Drug, and Cosmetic Act (FDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) remain firmly embedded in the law books, with no solution in sight. Indeed the legal battle continues to move along in the courts, most prominently the Court of Appeals which is hearing the NRDC challenge to EPA's handling of several tolerances which seem to violate the Delaney Clause.

Although mountains of data keeps pouring into EPA, significant datagaps persist and the lag-time between submission and review of data and resulting regulatory actions is growing longer -- except in the few "hot button" cases each year which EPA focuses on because of inordinate concern about risk or great pressure from the outside.

So I think it is healthy, and about time to turn the pesticide regulatory tables all the way around to where the rubber hits the road -- in the fields and orchards and on the farms of America. Legal struggles are important, but they never solve anything in and of themselves. But when a farmer adopts a new biological control

practice, or perfects an IPM system, or shifts a crop rotation so that pest pressure is markedly reduced, tangible progress occurs. Its time to encourage and reinforce these one-field-at-a-time victories, so that American agriculture can move out from under the cloud of suspicion that -- pardon the pun -- threatens to poison the well.

I hope that the environmental community, particularly individuals committed to activism and determined to make things change, will come to accept that farmers are their best and most important allies in efforts to reduce pesticide use and related hazards. For this reason, I urge the subcommittee to think creatively about the elements of a safer pesticide policy -- a policy designed to accelerate the adoption of biologically based crop protection systems that reduce pest pressure and rely heavily upon good management to limit the ecological niches available to damaging pests.

By directing attention toward the substance of a safer pesticide policy, you may be pleasantly surprised to find much agreement and enthusiasm to move forward among a broad diversity of groups -- including most environmentalists and the industry. You surely won't find such agreement as long as the focus of the debate stays riveted on negligible risk, pre-emption issues, and the Circle of Poison.

Another Critical Shift Needed

There is another fundamental change needed in pesticide regulatory policy if farmers are to retain access to several dozen widely used pesticides. Under current programs and policies, there is little enforceable discipline in <u>how</u> a registered pesticide is used. Most farmers and applicators follow the label, but most labels allow for both heavy and repeated applications. Some of the worst episodes of environmental damage in the last few years -- like Louisiana's fish kill -- were the result of legal applications.

There are several relatively toxic materials on the market today that are vital tools in IPM systems, products that pose little or no risk when used judiciously in a well-managed IPM system. Yet these same products can and are being used in ways allowed by pesticide product labels that pose clearly unacceptable risks to --

* Groundwater when applied on sandy soils or when excessive rainfall soon after application leaches the chemical through the root-zone just a few weeks after application;

* Fish or waterfowl when pesticides are picked up by surface water flows and carried into wetlands or estuaries;

* Farm-workers if they re-enter a field too early or are unaware of the type of product that had been applied.

We face a basic choice. If we continue down the path we are on, regulatory agencies will have to balance risks and benefits based upon how pesticides are used -- which is not always as carefully as they should be. Regulators will be forced to estimate risks based on conditions of use that have been observed and which are known to occur. Routinely these plausible "worst case" but nonetheless valid actual risk levels will exceed by several-fold the level of risk associated with the majority of applications of a pesticide. But if regulators have no way **beyond the label** to control or influence how and when pesticides are used, the system will invariably lead to more suspensions, more cancellations, and more severe restrictions that seem warranted given the average level of risks observed in the field.

So we are approaching a cross-roads. If we follow down the present path regulation will markedly thin out the ranks of registered pesticides, leaving only those that are relatively non-toxic and which are fairly forgiving. These are often referred to as environmentally friendly, and fortunately we do have several effective products that clearly deserve that label.

But most currently registered fungicides will go by the wayside, several the acutely toxic, hot organophosphate insecticides will be severely curtailed in use, and a number of herbicides -- especially those showing up routinely in water -- will attract the attention of regulators. Big trouble could emerge just a little bit farther along this road as farmers become reliant on just a few pesticides to control certain families of pests.

As the number of crop protection tools shrinks, the ability of pests to adapt resistance or otherwise get around a pesticide will grow. As we place more pressure on the environmentally friendly products on the market, we increase the chance that we will undermine their effectiveness.

We can choose at this cross-roads to take another path. We should decide as a matter of policy to reduce pesticide use and related risks through a judicious mix of regulation **and** encouragement of changes in farming practices and crop protection systems. We need to help farmers and crop protection specialists use biology more creatively in managing pests at tolerable levels with a much softer chemical touch. But to move down this path, regulatory policy must change. Research priorities must change. For these things to happen, laws must change, and hence the importance of this hearing.

One great advantage of moving down this path more aggressively is that for many crops in many regions significant progress can be achieved within just a few years. Also, this is the direction

farmers are already moving -- and are eager to move in faster, as soon as new biorational control products become available and as soon as the y gain confidence in the effectiveness of biologically based control strategies. This direction is clearly consistent with the EPA's current emphasis on pollution prevention, and with the USDA's commitment to make tangible progress in assuring that the American food supply is the safest available anywhere in the world.

But the solely regulatory path remains cluttered with procedural and legal battles unresolved, datagaps, the need for new science, and seemingly endless reviews by all sorts of groups.

We also must remember that the entire regulatory infrastructure is designed to make narrow risk-benefit determinations one pesticide, one crop at a time. The way we regulate pesticides has nothing to do with the way a pest, or a pesticide alters the biology of a cropping system, or vice versa. The tools we have to enforce the will of regulators -- pesticide labels and use restrictions -- are one-dimensional, red light/green light controls imposed upon a system which is far more dynamic and complex and interactive than can possibly be captured on a pesticide label.

And more and more, **unintended** consequences of regulation -- like the minor use problem and accelerated resistance -- are becoming more serious problems than the problems which gave rise to the regulation in the first place. Put simply, more and more regulatory actions and policies are doing more harm than good. In defense of EPA and state regulators, they are not unaware of these problems, and they are concerned and dedicated to trying to achieve safer, more sustainable crop protection systems. But regulators are locked within the confining bounds of the laws and policies they are responsible for caring out. These laws were not crafted with the biology of a cropping system uppermost in mind.

There's a favorite saying often heard in the halls around the Ag Committee -- "if it ain't broke, don't fix it". Well, from the perspective of farmers the system **is** broke and now threatens to break them if somebody does not wake up and hear the music. Its time for a change.

During the hearings scheduled over the next two months, the subcommittee will hear many suggestions about how to fix the system. It will be important to resolve Delaney's paradox, finally putting to rest the can of worms this subcommittee opened in 1982 during its oversight of changes in EPA's cancer policy.

Witnesses today will provide a report from the front-lines -- describing in some detail the challenges currently facing growers and their crop protection specialists **this year** in the field. Others will discuss some of the steps they have taken or are

considering to accelerate the rate of adoption of biologically based crop protection systems.

To help set the stage for today's hearings and those to follow, I present in the next section an abbreviated synopsis of major developments over the last decade that have shaped the challenges before the Congress today. As you will see from the chronology, the activities of this subcommittee have contributed steadily and constructively for over a decade, both in helping uncover information needed to understand the issues, as well as in crafting legislative solutions. **The lack of progress in passing legislation is a reflection of divisions in our society, not a lack of effort by the Congress or this subcommittee.**

I then discuss some of the critical science and policy choices that the Congress must make in deciding how to resolve Delaney's paradox. You will hear many people talk about negligible risk policy, yet I suspect that very few people really understand the essential ingredients of such a policy if it is to be meaningful and workable.

Last, I offer a brief overview of the four major proposals on the table -- the Rose bill, H.R. 3472; the Waxman-Kennedy bill; Bruce-Biley; and the Administration's phantom food safety proposal.

What a Long, Strange Trip Its Been

An incomplete and brief history of key events that have shaped the pesticide regulatory challenges before the subcommittee now follows. I apologize for leaving out many other important events, but hope this listing gives the subcommittee a feel for rich history behind today's legislative challenges.

1911-- California passes legislation establishing the nation's first state pesticide regulatory program -- one year after comparable federal legislation.

1947-- Major amendments passed to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), establishing the basic features of current law.

1952-- The Congressional Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, chaired by Congressman Tom Delaney, completes its work and releases a report calling for significant amendments to existing law, especially in the area of processed foods.

1954-- Congress adopts section 408 of the Food, Drug, and Cosmetic Act (FDCA), allowing for a consideration of pesticide benefits in setting tolerances for residues in or on raw

agricultural commodities.

1958-- The Delaney Clause--imposing a zero-risk standard for residues in **processed foods**--is adopted as part of amendments changing the regulatory provisions and procedures applied to processed foods. Through its actions, Congress creates the statutory basis for a conflict in the standard applicable to residues of oncogenic pesticides that concentrate in certain processed foods.

1962-- Congress adds the DES Proviso to the Delaney Clause which allows FDA to approve an animal drug that may leave a residue as long as no residues can be detected using analytical chemistry methods acceptable to FDA. This proviso leads to the **sensitivity of the method** exemption to the Delaney Clause as long as a detectable residue of a drug poses risks no more than one in one million.

1972-- Congress passes legislation establishing the modern pesticide regulatory framework. Pesticide uses are **registered** if the benefits of use are found to exceed risks.

1980-- The U.S. Court of Appeals describes and relies on the **de minimis** doctrine in a ruling that exempted Alabama Power from strict application of a provision of the Clean Air Act.

June, 1981-- The first major legislation proposing significant reform of the Delaney Clause, S. 1442, is introduced, The bill's complexity and the unfolding political crisis in the EPA stall its progress toward passage.

December 5, 1984-- EPA publishes in the Federal Register a regulatory decision establishing a section 409 tolerance for dicamba, a pesticide with an oncogenic nitrosamine metabolite. The agency cites FDA's **constituents policy** in establishing the tolerance.

February, 1985-- EPA commissions the National Academy of Sciences (NAS) to examine the impact of the Delaney Clause on pesticide tolerance setting and EPA decision-making.

June, 1985-- FDA announces its intention to not apply the Delaney Clause to very small, **de minimis** risks posing less than a one in one million risk of an additional case of cancer.

August 7, 1986-- The FDA adopts a **de minimis** interpretation of the Delaney Clause in a key color additive decision.

1987-- Public Citizen challenges the FDA's application of a **de minimis** exemption in the color additive case. The Court of Appeals upholds the FDA's decision and an attempt by

petitioners to bring the case before the Supreme Court is unsuccessful.

June 8, 1987-- Hearing before the Congressman Henry Waxman's Subcommittee on Health and the Environment exploring the recommendations of the NAS report and recent EPA decisions.

May, 1987-- National Academy of Sciences releases **Regulating Pesticides in Food: The Delaney Paradox.** A series of Congressional hearings assess the report's recommendations, and lay the groundwork for the major legislative proposals introduced since 1988.

October 23, 1987-- U.S. Court of Appeals decides in the Public Citizen vs. Young case that the Delaney Clause precludes FDA from applying a **de minimis** exemption to color additives.

1988-- Passage of the so-called "FIFRA-Light" legislation which set a firm schedule for pesticide re-registration and established a new fee structure to help pay for EPA regulatory activities. After three years of intensive debate, Congress fails to reach consensus on a number of other legislative issues, including what to do about the conflicting standards applied to oncogenic pesticide residues in food.

June 28, 1988-- Congressman Pat Roberts introduces H.R. 4937, "The Pesticide Food Safety Act of 1988"

September 7, 1988--The Subcommittee on Department Operations, Research, and Foreign Agriculture (DORFA), House Committee on Agriculture holds hearing on H.R. 4937 and the recommendations of the 1987 NAS report

October 19, 1988-- EPA publishes in the Federal Register a notice announcing agency policy in response to the 1987 NAS report. The policy states that "EPA's position will be that section 409's so-called Delaney Clause...is subject to a **de minimis** exception where the human dietary risk from residues of the pesticide is at most negligible.

October 25, 1988-- President Reagan signs PL 100-532, the so-called FIFRA-Lite bill reforming the pesticide re-registration process

May 17 and 31, 1989-- Two hearings held before Congressman Waxman's Subcommittee on Health and the Environment on H.R. 1725, the so-called Kennedy-Waxman bill which would amend section 409 to apply a negligible risk standard to pesticide residues and remove consideration of benefits from setting all pesticide tolerance levels, including those under section 408.

May 23, 1989-- The State of California, Natural Resources Defense

Council (NRDC), Public Citizen, the ALF-CIO, and several individuals file a petition with the EPA requesting that the agency revoke 11 food additive tolerances established under section 409 of the FDCA which, according to petitioners, violate the Delaney Clause.

May, 1989-- Two hearings held before Congressman Waxman's Subcommittee on Health and the Environment on H.R. 1725, the so-called Kennedy-Waxman bill which would amend section 409 to apply a negligible risk standard to pesticide residues and remove consideration of benefits from setting all pesticide tolerance levels, including those under section 408.

June 6, 1989-- Hearing before the Senate Committee on Labor and Human Resources on S. 722, Senator Kennedy's food safety bill, companion legislation to H.R. 1725.

October 19 and 31, 1989-- Hearings are held before the DORFA Subcommittee, House Committee on Agriculture on H.R. 3292 (De La Garza bill) and H.R. 3153 (Brown bill).

October 26, 1989-- President Bush unveils the Administration's seven part **Food Safety Plan** calling for major revisions in FIFRA and FDCA to "eliminate a long-standing inconsistency in the law...and establish(ing) a `negligible risk' standard..."

February 5, 1990-- EPA transmits to the Congress draft legislative language to implement the President's seven-point food safety initiative.

April 19, 1990-- EPA denies most of the NRDC et al petition calling for revocation of several section 409 tolerances. The agency reaffirms its commitment to a de minimis exclusion from the Delaney Clause when a pesticide poses less than a negligible risk.

October x, 1990-- Senator Lugar introduces S. 2490, "The Pesticide Safety Improvement Act of 1990."

February 25, 1991-- EPA publishes Federal Register Notice refusing to revoke several section 409 tolerances that, according to an NRDC petition, violate the Delaney Clause. In justifying its actions, EPA cites and defends its new negligible risk policy adopted in response to the 1987 NAS report.

May 14, 1991-- Congressman Henry Waxman introduces the third major revision of the Waxman-Kennedy bill, the "Safety of Pesticides in Food Act of 1991".

August 2, 1991--The "Food Quality Assurance Acto of 1991", H.R. 3216, is introduced by Congressman Bruce.

November 7, 1991--Congressman Charlie Rose introduces H.R. 3742, the "Pesticide Safety Improvement Act of 1991".

November 19, 1991--The DORFA Subcommittee holds a public hearing on H.R. 3742, with administration witnesses only. Testimony is presented on behalf of EPA, FDA, and USDA.

Science, Policy, and Politics

Science and politics rarely mix well, yet it happens everyday in democratic societies. Whether we like it or not, scientific knowledge is not perfect. Many visible issues that people care a lot about -- like food safety -- invariably involve tradeoffs between competing social needs. Science can inform the consequences of these tradeoffs but can't prove what is "right."

Congress always faces a difficult challenge when it has to deal with risk and uncertainty. The task is even more difficult when motivated constituencies have a political stake in convincing the Congress, by convincing the public, that their view of the "facts" is the more correct.

Most people accept that scientific issues should be assessed, debated, and resolved through an open process of dialogue and reflection among experts. In contrast, matters of public policy -- choices which have to be made between competing interests and conflicting goals -- can only be resolved within a political process, open and responsive to whatever views and concerns exist within society.

Policy issues force the political process to confront choices. Policies that do not reflect society's values and concerns fall out of favor and are eventually changed. This is the process underway in the area of food safety reform, a process with lots of history but relatively little consensus, at least until recently.

Defining the nature of the risk policy that should govern the setting of pesticide tolerances is probably the most contentious and fundamental pesticide policy issue that must be resolved by the Congress. Most people agree now that such a policy should establish and somehow enforce a negligible risk level, but widely differing views persist regarding how to do so and how and when to bring existing pesticide tolerances into compliance with the new policy.

This task poses tough policy choices before this subcommittee, and difficult scientific issues for those who are asked or offer to advise the subcommittee on what we know or don't know about pesticide risks in food. What are the essential components of a

negligible risk policy? How will it work in practice? What might its impact be?

I remember clearly several years ago during a hearing before this subcommittee when Chairman Brown, in response to a particularly insightful panel urging action by the Congress to address some problem, said: "Even for great minds like those on this subcommittee, it helps to understand a problem before trying to solve it." This is very good advice for this subcommittee as it takes on the difficult responsibility of incorporating into law a sensible resolution of Delaney's paradox.

The Nature of Negligible Risk The idea behind a negligible risk policy is that there are many risks so small that they do not really amount to anything worth worrying about. No one should change their behavior to avoid them. Government should not impose costs on society to reduce them.

But how does one tell whether a given pesticide poses only a negligible risk? And who is to decide what level of risk is acceptable?

The answer to the last question is easy -- only the people of the country can decide through you, their elected representatives.

A negligible risk policy is a set of standards, rules, and procedures designed to achieve a certain goal -- assuring the absence in the food supply of unacceptable risks associated with the consumption of pesticide residues.

THE GOAL

The first step in defining such a policy is to state its goal. A policy without a goal is like a tail without a dog.

A negligible risk policy could strive to:

* Assure that each pesticide use on each individual crop is safe, that is each pesticide-crop combination poses no more than a negligible risk.

* Assure that exposure from all the crop uses of each pesticide, when added together, poses no more than negligible risk.

* Allow all registered uses of all pesticides to pose no more than a negligible risk.

Note that all three goals use the same sort of decision-rule--a risk standard is set and applied to some definition of exposure. A stricter negligible risk policy -- one that would result in more suspensions and cancellations -- would result either from establishing a lower level of acceptable risk, or by expanding the

number of crop uses including in the estimate of exposure, and/or through both mechanisms. Likewise, a less strict policy could be put in place by choosing a higher risk level and/or applying it to a smaller number of crop-pesticide uses.

The first goal stated above is pretty close to the provisions in H.R. 3742; the second goal is how EPA explains its current policy; and the third would be extremely risk averse and would result in wholesale cancellations, and is roughly analogous to the provisions of the Waxman-Kennedy bill.

A negligible risk policy goal could also be stated in terms of a specific percentage reduction in risk from current levels; or, the policy could define the maximum allowed risk from all pesticide residues in the diet, and stipulate how the agency must proceed -- and how fast -- toward reducing tolerances until the goal is reached.

Such goal statements would accept as the point of departure the current **size** of the balloon, and stipulate a set of rules regarding how some risk should be squeezed out of the balloon. Specific rules would, in turn, determine the allowed **shape** of the balloon as it is shrunk down in **size**.

ACCEPTABLE LEVELS OF RISK

A second dimension of a negligible risk policy is where and how to draw that proverbial line in the sand. How safe is safe, anyway?

There are **two** intertwined components of this question -- one makes no sense without the other. Whenever someone comes before the subcommittee with a proposal regarding negligible risk, be sure to ask them two simple questions:

* What quantitative level of risk do you consider acceptable?

* In deciding whether estimated risks are above or below the quantitative risk level specified above, what unit of exposure will be used in estimating risk -- that is, one crop use at a time, or all registered uses of a single pesticide, or all pesticides or just processed foods?

Let me emphasize again that it is meaningless to form an opinion of a risk level someone might propose until they also specify what the unit of exposure will be. Several constituency groups, and perhaps more than one member of Congress have stated strong views about acceptable levels of risk without specify or understanding the significance of specifying the unit of exposure. Stated differently, a very strict risk standard can be made loose as a goose, or a seemingly lenient standard very binding by changing the definition of the unit of exposure to which the risk

standard will be applied.

To understand the **practical** differences between H.R. 3742 (the Rose bill), the Bruce-Bliley bill (H.R. 3216), and the Waxman-Kennedy bill (H.R. 2342) the subcommittee must keep asking this question about what the unit of exposure is to which a proposed negligible risk standard is to be applied.

MEASUREMENT OF EXPOSURE

After defining what the unit of exposure will be, additional key questions are faced in deciding how to measure it. Accordingly, a negligible risk policy will need to also settle the following questions:

* Risks to whom? What population group is to be used as the basis for determining whether a negligible risk level is exceeded?

* Will the standard apply to the amount of a given food eaten by an average eater, the average of all people (including people that do not eat a given food), the average amount eaten by the 5 or 10 or 20 percent of the population that eat the most of a given food, or what?

These questions get at one of the essential policy decisions embedded within the details of the risk assessment process -- what percent of the population should regulators strive to protect and how thoroughly should unique risks faced by just a segment of the population -- like infants, pregnant women, or the elderly -- be taken into account.

ESTIMATION OF RISK

Once all the above questions have been settled, only three basic questions remain. The first two involve the criteria and methods used to make the estimate of risk from a given amount of exposure; the third deals with how certain regulators should be that their estimates of risk do not **underestimate** actual risk levels:

* How should the unique physiological risks faced by certain special population groups be taken into account?

* What triggers the need for an oncogenic risk assessment to be carried out? How does one interpret the key phrase in the Delaney Clause "found to induce cancer"?

* What level of uncertainty should regulatory officials accept? That is, how certain must they be that a given use of a pesticide will not pose a risk above the negligible risk level?

RISK REDUCTION

A last critical dimension of a negligible risk policy defines how the rubber will hit the proverbial road -- what EPA does when it finds that a pesticide poses risks above a negligible level. In such cases, FIFRA requires the agency to address two more questions:

* How will all pesticides on the market and all new products in the regulatory pipeline be brought into compliance with the negligible risk standard defined by the answers to the above questions?

* Do the benefits outweigh the risks?

And in order to address this last question, the agency has to settle a few more questions -- benefits to whom? How should benefits be empirically measured and then weighed against projected changes in the rate of occurrence of certain adverse health effects? Negligible relative to what? Smoking? Skydiving?

Science and Policy Intertwined The establishment of a negligible risk level, and a regulatory policy mechanism to bring all tolerances into accord with it, raises a number of inseparable science and policy choices. Some questions -- like defining a negligible risk level -- can only be resolved within a political context since the questions involve balancing attainment of competing social goals. Science, thoughtful analysis, and logic can **and must** clarify the inherent choices that have to be made, but in the end science can not prove what is right or fair in the tradeoffs that have to be made.

Some progress had been made by the close of the 101st Congress in settling certain critical questions essential in defining the nation's negligible risk policy for pesticides. Many tough choices remain, as you will be reminded in the next hearing which will focus on risk issues. One of the most difficult and timely is safe to whom? Infants and children for example?

Legislation proposed by Chairman Rose (H.R. 3742, see section 205 (c)(2)(D)) defines Negligible Risk as:

"(ii) with regard to... (oncogenic risk), if the level of dietary exposure to a residue in or on a particular food to a person in the 90th percentile of consumption of that food is at or below a level that the Administrator has determined will present at most a negligible increase in the lifetime risk to such a person of experiencing such an adverse human health effect.

For the purposes of clause (ii), an increased risk shall be considered negligible if the Administrator determines that the upper bound increase in risk to such a person from lifetime dietary

exposure to the residue, determined by reasonable methods, does not exceed one in one million."

This language (which is almost identical to the comparable provision in Senator Lugar's draft legislation) provides a clear answer to the consumption side of the "safe to whom?" question. Some people may argue in support of a different percentile, for example environmentalists who believe risks need to be markedly lower might insist that EPA use the 95th percentile of consumption. Agricultural interests are likely to argue this is far too conservative an approach, favoring instead some other definition like the mean of eaters of a particular food, a measure that results in a significantly lower estimate of consumption.

Uniquely Sensitive Population Groups As the subcommittee is aware, an explosive report entitled Intolerable Risk issued by the Natural Resources Defense Council in 1989, and two 60 Minutes episodes on Alar soon thereafter focused intense media and public attention on pesticide risks to infants and children. The after-shocks continue.

A major National Academy of Sciences study has been commissioned by EPA, and is scheduled for completion in mid to late 1992, if no further problems are encountered. If the NAS report is responsive to the charge given to it by EPA, the report will review and recommend the assumptions and risk assessment methods EPA should either apply or develop in order to more accurately estimate risks to infants and children. On the basis of the report's recommendations, EPA should be able to move ahead with specifying the formula it will use in calculating "child adjusted risks". Once this formula is set, it will be a simple mathematical task to calculate "child adjusted tolerance levels" consistent with whatever level of risk the Congress and/or EPA defines as negligible.

Dealing with Uncertainty What should regulators do, if anything, when scientific uncertainty is pervasive, and while improved knowledge is being developed? Should they expand margins of safety? Collect more data in an effort to eliminate blind spots? Invest in basic science to develop better methods to test for and quantify risks?

In making choices about such steps, the Congress needs to weigh the ability of science to target efforts effectively so that there is a reasonable degree of assurance that increased investment of regulatory and scientific resources, both in the public and private sector, will deliver tangible and clearly positive results. My advice to you is to be skeptical if **anyone** sounds very certain about pesticide food safety risks.

Cumulative and Synergistic Risks Scientists and consumer activists have long worried about the possibility that the risks

from different pesticide residues might somehow be synergistic, or at least cumulative. Scientific bodies exploring this concern have generally concluded that while such a possibility exists, there is no basis for significant concern, with a few clear exceptions where pesticides are closely related chemically, and in their toxicological properties.

Some pesticides contain or quickly break down to the same toxic metabolite, or moiety using a chemist's terminology. One example of a group of pesticides which pose clearly cumulative risks are the four ethylenedisditiocarbamate fungicides (EBDC's) maneb, zineb, mancozeb, ziram. EBDC fungicides breakdown to a common chemical -- ethylene thiourea, or ETU. All risk assessments, and resultant regulatory decisions on the EBDC's are done on the basis of cumulative ETU residues.

The organo-phosate (OP's) and carbamate insecticides are the most important cluster of pesticides likely to be treated similarly. There are several dozen of these products, some of which are very acutely toxic and which must be handled very carefully by applicators. Both classes of pesticides can cause cholinesterase inhibition in exposed individuals, along with a long list of other minor to serious ailments. The scientific case for adding together estimated dietary exposure to the OP's and carbamates is clearly gaining momentum, and will no doubt be addressed in the forthcoming NAS study.

What About Benefits? The basic decision-rule within the FIFRA statute requires EPA to balance risks and benefits. As described at length in Regulating Pesticides in Food: The Delaney Paradox, the role of benefits within the EPA regulatory process is both controversial and puzzling to sort out. A just released General Accounting Office report entitled "Pesticides: Better Data Can Improve the Usefulness of EPA's Benefit Assessment" criticizes several aspects of EPA's benefits-assessment methodology.

In deciding whether to grant a new registration, EPA really does not consider prospective benefits. To do so would be a difficult analytical challenge since EPA would have to predict the degree of farmer acceptance of the product, which is in turn contingent on pricing and marketing strategies which are not defined fully until after registrations are granted by EPA. Moreover, EPA would have to predict field performance under the widely different conditions that exist across the country. So, for sound reasons, benefits really do not play a role in the granting of new registrations.

Benefits come into play when EPA is evaluating whether to alter the registration of a product currently on the market. EPA strives to estimate the net change in farm income as a result of a regulatory restriction on a particular pesticide. It does so by evaluating the cost and effectiveness of the next best available

product, and comparing those costs and returns to the grower to the costs and returns received with the product under review. The two key variables are effectiveness of control and cost of the product relative to other registered alternatives.

EPA has been criticized for years for its narrow definition of pesticide "benefits." Many individuals and organizations have made the case that EPA should be much more inclusive in estimating the gross and net economic consequences of pesticide regulatory actions. The recent GAO report echoes these concerns and recommendations.

Also, as currently undertaken by EPA benefits assessments do not include a wide enough range of alternative cultural, biological, and genetic options farmers could chose to reduce pest pressure if a particular pesticide is canceled. Again, key implicit questions are "Benefits relative to what?" and "Benefits to whom?"

Most people now agree that the EPA's current benefits policy and methodology is difficult to defend. Reflecting this consensus, the President's October 1989 food safety plan proposed a significant change in the nature of benefits that would be considered in setting pesticide tolerance levels. Instead of economic benefits in terms of net profits to the farmer, the President's plan called for consideration of other sorts of benefits to the consumer and society. Specifically, the Presidents plan proposes that the EPA Administrator "consider", when determining whether to set a tolerance above a negligible level whether:

* The risk to human health would be greater in the absence of the pesticide because of heightened levels of some natural carcinogen or contaminant, for example aflatoxin.

* The risk from alternative pesticides is greater.

* The cost of food to consumers would put key fruit and vegetable, or other food products, out of the reach of poorer families.

* Farmers would suffer excessive losses.

* Reasonable efforts are being made to develop alternative control technologies.

At least some members of Congress have been responsive to this component of the President's proposal. H.R. 3742, Bruce-Bliley, and Senator Lugar's bill include language patterned after these new types of benefits. The Kennedy-Waxman bill eliminates any consideration of benefits. Accordingly, when legislation finally passes, a substantial change seems likely in how benefits are

defined. Impacts on agricultural production expenses and returns will receive less attention and human health effects will rise in prominence.

A Comparison of Four Legislative Proposals

Four principal, distinct legislative proposals have emerged and evolved since the release of the 1987 NAS report -- each proposing an alternative path to implement the report's recommendations. Each bill contains different combinations of provisions including: procedural changes, amendments streamlining cancellation and suspension provisions, new fees and penalties, authority for new research activity to develop integrated pest management systems and address the unique crop protection needs of minor crop producers, national uniformity, provisions addressing inert ingredients, among several others.

Administration Food Safety Plan During 1988 and 1989, the level of pesticide regulatory activity was very brisk as legislators crafted bills. Executive branch agencies tried in vain to agree on a Administration bill. Divisions between USDA and EPA aggravated and reinforced divisions on the Hill -- a problem that thrives to this day. The EPA struggled to complete Special Reviews and re-registration actions on some of the key, older pesticides known to pose risks well above just about everybody's definition of negligible risk.

But with so many critical policy issues unresolved and the Congress seemingly posed to act, the EPA was reluctant to take final actions on any major products. And then came the first Alar episode on the CBS news program "60 Minutes", and the release of NRDC's Intolerable Risk report. The already brisk pace of events almost immediately became chaotic.

In order to calm troubled waters, and hopefully break the legislative logjam, the Administration took the unprecedented step October 26, 1989 of releasing from the White House a Presidential Food Safety Plan. The announcement from the White House Office of the Press Secretary said:

"The President's plan calls for major revisions to the FIFRA and FFDCA...will streamline EPA's ability to remove potentially hazardous pesticides from the market...would eliminate a long-standing inconsistency in the law governing pesticide residues in food, and establish a "negligible risk" standard for such residues."

Despite the release of the Presidential plan, Executive branch agencies still had many detailed issues to work through in crafting specific legislative language. This process proved much more

difficult than anticipated. Indeed, the Administration has still not completed its work on a consensus bill.

In the spirit of advancing consideration of the President's food safety plan on the Hill, Senator Lugar developed a comprehensive legislative package addressing each of the plan's seven ares. S. 2490, "The Pesticide Safety Improvement Act of 1990", was introduced by Senator Lugar on April 20 1990. Its basic provisions are reviewed next.

The President's Food Safety Plan and the Lugar Bill

During 1988 and 1989 in a half-dozen Congressional committees, the pace of pesticide oversight and legislative activity was brisk. Hoping to help provide guidance, focus, and impetus to the process, the Bush Administration engaged in an internal dialogue culminating in a seven-point food safety initiative announced on October 26, 1989.

Despite the release of the Presidential plan, Executive branch agencies were unable to agree on legislation. But they did pledge to work with members of Congress developing their own proposals and asked Senator Richard Lugar (Repub.-Indiana) to consider crafting a bill built upon the seven-point Administration plan, which he did. Upon introducing S. 2490, Senator Lugar said:

"The legislation I introduce today reflects the seven points of the President's plan and is intended to restore not only consumer confidence but also the confidence of American farmers in the safety of the pesticides they use."

S. 2490 contains several provisions similar to another bill -- H.R. 3292 (the De La Garza bill) -- but went beyond any of the previously introduced bills in many areas. It tried to include language consistent with each of the seven points in the presidents food safety plan. The core features of S. 2490 were:

* Changes in the FIFRA cancellation and suspension provisions to expedite removal from the marketplace pesticides found to pose risks above an acceptable level.

* Requires collection of up to date actual residue and pesticide use data, as a means to continuously improve the accuracy of risk assessments.

* Provides for additional pesticide user training, especially where and when worker exposure or groundwater hazards exist.

* Establishes a negligible risk standard **in the range of one-in-one million;** requires that such a standard be applied one crop use at a time, and that exposure estimates be based on the 90th percentile of consumption (i.e. at a level at which 90% of consumers would be expected to consume less of a particular crop);

and, acknowledges that economic and health benefits to the consumer arising from changes in the availability of certain foodstuffs be considered in setting tolerances that might pose risks above the one-in-one million range.

* Provides for national uniformity in the establishment of tolerances a controversial provision in the President's food safety plan that would pre-empt a state's right to impose a stricter standard that the federal government in the setting of pesticide tolerances.

Since introduction of S. 2490, Senator Lugar's office has been monitoring developments within the Executive branch and working on a refined version of the legislation, which is likely to be much like H.R. 3742 when finally introduced.

The Waxman-Kennedy Bill Three weeks after the release of the NAS report Regulating Pesticides in Food: The Delaney Paradox, Congressman Henry Waxman (Dem.-California), convened a hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce. A member of the NAS committee that authored the report, Mr. Richard Merrill presented testimony summarizing the recommendations of the NAS report. Government, food industry, and consumer group witnesses offered their reactions to the report and their perspectives on the need for legislative reform.

In late 1987 and early 1988 Congressman Waxman and subcommittee staff undertook an indepth assessment of the legal issues underlying Delaney's paradox and concluded that legislation was in fact needed. Staff of the Senate Committee on Labor and Human Resources carried out a comparable exercise, leading to the introduction of the first version of the Waxman-Kennedy bill.

The Waxman-Kennedy bill has progressed through three major iterations. On April 6, 1989, Mr. Waxman introduced in the House the second version, "Food Safety Amendments of 1989" (S. 722 as introduced by Senator Kennedy). The third iteration, H.R. 2342, was introduced May 14, 1991 by Congressman Waxman, and is called the "Safety of Pesticides in Food Act of 1991." (S. 1074 was introduced May 14, 1991 by Senator Kennedy).

The so-called Kennedy-Waxman bill contains provisions most enthusiastically endorsed by environmental and public health groups advocating an elimination of benefits considerations in setting tolerances, coupled with consistent application of a negligible risk standard. The Kennedy-Waxman bill includes a series of decision-forcing mechanisms that would rapidly compel the EPA to progressively reduce, in three stages, estimated oncogenic risks in the diet down to no more than one-in-one million, for all registered pesticides.

The first phase of risk reduction would mandate that within 3 years individual tolerances be set so that the risk from each individual crop use of an oncogenic pesticide does not exceed one-in-one-million; then after three more years, the risk across all crop uses of each pesticide would have to be reduced to no more than one in a million; and last, the cumulative sum of risk across all pesticides would have to be reduced to no more than one in a million.

The provisions of the Kennedy-Waxman bill went well-beyond the recommendations in the NAS report in several respects. Some of these stricter provisions were relaxed or eliminated in later versions of the bill, for example a major section imposing new regulatory requirements on inert ingredients in pesticide products.

The principle alternative to the Kennedy-Waxman bill, H.R. 4937 in the 100th Congress emerged from activities within the House Committee on Agriculture.

House Committee on Agriculture The stage was set for legislative action within the House Committee on Agriculture in the 100th Congress by a series of oversight hearings and reports issued form 1982-1985 by the House Committee on Agriculture's Subcommittee on Department Operations, Research, and Foreign Agriculture (DORFA), then chaired by Congressman George E. Brown. This subcommittee's efforts initially brought Delaney's paradox into public light and played a catalytic role in the EPA decision to seek the assistance of the NAS.

The subcommittee's activities focused in the mid-1980s on the slow pace and what people felt were serious deficiencies in the re-registration process. A major effort to fashion a compromise bill was made in 1985-86 by the National Agricultural Chemicals Association (NACA), representing industry, and the Natural Resources Defense Council (NRDC), a major environmental organization.

H.R. 4364, a major and comprehensive piece of legislation, was the end result of a long and arduous series of negotiations. But the bill was passed in somewhat differing forms by the House and Senate, requiring a conference committee. Very late in the session, when all but a few tangential issues had been resolved, a few recalcitrant Senators blocked final action and a nearly successful two-year effort at compromise--the last serious effort made--fell short at the close of the 99th Congress.

The House agriculture committee began the legislative cycle in 1987 with little enthusiasm, having invested a great deal of effort in passing H.R. 4364, only to have the bill die at the very last moment despite broad-based, sincere support for most of its major provisions. Moreover, other issues--like the farm income and credit crises--were commanding the committees attention.

On June 28, 1988 Congressman Pat Roberts (Repub.-Kansas) introduced H.R. 4937, the "Pesticide Food Safety Act of 1988", the first of several bills emerging from members of the House Committee on Agriculture. In introducing H.R. 4937, Congressman Roberts said that "we have a real need to return to the policies and processes that govern the safety of pesticide residues in our Nation's food supply...Yesterday, I introduced a bill that would implement a list of well-publicized recommendations developed by a panel of experts at the National Academy of Sciences." One hearing was held on the bill in 1988 which led to no further action.

Throughout 1988, the House focused most of its attention on passing FIFRA-reform legislation dealing with the core re-registration issues that had almost been resolved by passage of H.R. 4364 in the 99th Congress. To increase the chances of success in the 100th Congress, staff compiled a bill containing only provisions passed earlier by either the House or Senate. There was little or no support for trying to include food safety reform amendments in the legislative package.

The strategy to proceed with a core, consensus bill proved successful. President Reagan signed Public Law 100-532 on October 25, 1988, the so-called FIFRA-Lite bill which accelerated the re-registration process, established a schedule of fees, and addressed a number of other procedural issues. (For a thorough discussion of the process leading to passage of this bill, as well as an indepth explanation of its content, see the special report by the Bureau of National Affairs, Regulating Pesticides: FIFRA Amendments of 1988, by Janice L. Greene).

In 1989 focus returned to food safety reform. Congressman De La Garza introduced H.R. 3292, a revised and expanded version of Congressman Roberts bill from the year before. This bill was supported by the farming, food, and agribusiness communities and from most members of the agriculture committee. It was, not surprisingly, opposed in whole or part by the environmental community. While the bill tracked the NAS report recommendations, it provided the EPA more procedural and scientific latitude than skeptical environmentalists' thought desirable.

On August 4, 1989 then Chairman of DORFA Congressman Brown advanced a new proposal, H.R. 3153. While Mr. Brown's bill was less comprehensive than other proposals, it contained several innovative provisions, several of which have been incorporated in the suspension/cancellation and minor crop use provisions of H.R. 3742.

But the Brown bill's most novel provision -- a ten-year sun-set provision on registrations -- has received little or no attention or discussion since 1989.

Section 3, subsection (d) states:

"(1) Expiration of Registrations.-

(A) Duration of Registrations.- Notwithstanding any other condition imposed on the registration of a pesticide product, the registration of a pesticide product that has not been canceled or has not otherwise expired shall automatically expire in accordance with the provisions of this paragraph."

The section goes on to specify a 10-year sun-set period, and explains the procedure that a registrant must follow to get a new 10 year registration when the end of a current registration is reached.

The crux of this proposal is that once every 10 years, pesticide registrants must submit a complete, up to date data package, and meet the contemporary standard regarding the degree of risks deemed acceptable in light of corresponding benefits. Registrants would be required to generate new data only in cases where new requirements have been put in place, or when old studies are deemed no longer acceptable. This process of upgrading the dataset supporting registrations is now a routine part of the re-registration process.

This provision would accomplish an important change relative to dealing with the "old" pesticide problem. Current law is clearly biased against new chemicals since it is much harder now to get new chemistry registered than keep an old product on the market -- even one with significant evidence of hazards like aldicarb. But the sun-set provision would shift the burden of proof to the registrant, requiring pesticide manufacturers once every 10 years to prove that a pesticide meets current standards for safety and efficacy. While never brought to a vote, this provision was supported by some leading food and drug lawyers, including Mr. Michael Taylor who now serves in a key position as FDA's Deputy Commissioner for Policy. Also, note that this provision speaks directly to the third item in the President's food safety plan -- periodic review.

Hearings on the de la Garza and Brown bills were held October 19 and 31, 1989, although no further action was taken (see Serial No. 101-44, "Pesticide Regulatory Reform Amendments of 1989 and the Food Safety Assurance Act of 1989"). But by mid-1989, members of the agriculture committee were heavily involved in the process of crafting the 1990 farmbill, a major piece of legislation passed every five years re-authorizing and amending the nation's basic farm commodity, export, conservation, credit, research, and rural development policies.

A Comparison of Four FIFRA Reform Proposals

Four major legislative proposals are now briefly reviewed and contrasted:

* The Presidents Food Safety Plan, as amplified in the EPA document dated February 5, 1990, "Proposed FIFRA Language"

* H.R. 3742, "The Pesticide Safety Improvement Act of 1991" introduced November 7, 1991 by Chairman Rose

* The Waxman-Kennedy bill's third rendition, H.R. 2342 introduced May 14, 1991

* H.R. 3216, the Bruce-Bliley bill, entitled "The Food Quality Assurance Act of 1991", introduced August 2, 1991.

Each bill contains different combinations of provisions including: procedural changes, amendments streamlining cancellation and suspension provisions, new fees and penalties, authority for new research activity to develop integrated pest management systems and address the unique crop protection needs of minor crop producers, national uniformity, provisions addressing inert ingredients, among several others.

Acceptable Level of Risk The first key parameter that plays a central role in determining the consequences of a negligible risk policy is the level of risk which is judged acceptable. Risks estimated below such a level are deemed negligible, and hence allowed. Risks above the level are considered too high to accept on an ongoing basis.

It is important to stress here that when EPA concludes that a particular pesticide poses a chronic health risk above a negligible level, that does not necessarily mean that the pesticide poses a major and immediate risk of adverse health effects. It means that over a lifetime of exposure to the chemical, the added risk of disease, even though uncertain, is great enough to warrant a prudent steps to reduce exposures, and hence risk.

Remember also that the level of acceptable risk embodied in a negligible risk policy is meaningless without more details specifying how the standard will be applied and how risks will be estimated. In assessing the impact of the four proposals described in this section, focus should be directed to the **combined** impact of the elements within the proposal, not just the risk level or how consumption is measured or any other single element.

The President's plan proposes an acceptable level of risk "in the range of one in one hundred thousand and one in one million". Administration witnesses -- most recently Linda Fisher during her

appearance before DORFA on November 19, 1991 -- have explained that risks up to one in one hundred thousand, or higher **per pesticide across all its registered uses**, could be deemed acceptable when justified by the benefits accompanying use of a pesticide.

Except for pesticides registered on more than 10 crops, this is clearly a less conservative standard than proposed in H.R. 3742 and H.R. 2342. The subcommittee should be alerted to the significance of specifying whether a bill's negligible risk standard applies one crop use at a time -- as recommended by the NAS in Regulating Pesticides in Food: The Delaney Paradox and in H.R. 3742 -- or across all uses of a pesticide.

As pointed out by Linda Fisher November 19th in her testimony before DORFA, one of the distinct advantages of the one crop use at a time approach embodied in H.R. 3742 is that it would allow EPA to lighten up markedly on several minor uses which contribute very small increments to a pesticide's overall risk.

But there is another reason why the one crop use at a time approach is preferred -- the conventional approach leads to all sorts of unexpected consequences, including regulatory actions that increase risk, as documented in the NAS Delaney report. Curiously, when the NAS report first came out in 1987, the EPA clearly and repeatedly expressed support for the report's basic recommendation to apply a negligible risk standard one crop use at a time. At some later date, the agency apparently changed its mind by stating its intention to stick with the current policy -- assessing and regulating a pesticide's oncogenic risk across all registered uses.

Lessons throughout the 1980s -- the series of grain fumigant decisions, several fungicide decisions, among others -- demonstrated that such an approach is administratively and technically flawed. It is time for EPA to caste it aside once and for all. By passing H.R. 3742, you would give EPA the final push it apparently needs to abandon a mode of regulatory decision-making that too often results in bad decisions.

The Waxman-Kennedy bill proposes the strictest, most conservative standard. It is conservative in the sense of defining a clear, quantitative standard, coupled with a requirement that the Administrator must be convinced with "reasonable certainty" that residue levels from **all** uses of a pesticide pose no risks above a negligible level.

This standard is closely related to the standard applied by FDA in reaching food safety judgements under the FDCA's general safety clause. It would place a heavier burden on pesticide registrants to produce data which convincingly demonstrates the absence of any risks above one in one million.

H.R. 3742 proposes, for oncogenic pesticides, that a one in

one million negligible risk standard be applied to each crop use of each pesticide. The bill would allow EPA to distinguish between threshold and non-threshold effects when evaluating a pesticide's potential to cause cancer -- an important change in current policy which will reduce the severity of regulatory actions taken on those non-genotoxic (does not damage a cell's genetic material) pesticides causing an increase in tumors only at very high doses, and then usually only in one sex/species.

The Bruce-Bliley bill has the most flexible standard, which is expressed only qualitatively -- a tolerance may be established at a level "adequate to protect the public health." The Administrator is further instructed to incorporate "reasonable assumptions" in calculating risks. The bill's language would allow the EPA to exercise a considerable degree of discretion in determining how it will define and implement a negligible risk standard. Hence, it is difficult to say what would happen as a result of this bill's language. Clearly, it would allow, but does not mandate, the EPA to become much less conservative.

One of the most significant differences among the proposals is whether and on what basis the Administrator may set a tolerance that poses risks above the acceptable level of risk. Only the Waxman-Kennedy bill would prohibit, under any circumstances, such a tolerance to remain on the books. At the core of this provision in the Waxman-Kennedy bill is its elimination of the consideration of pesticide benefits in tolerance setting, one of the bill's most significant departures from current policy and law.

Consistent with FIFRA's basic risk-benefit balancing mandate, the Presidents's plan, the Rose bill, and Bruce-Bliley would authorize the Administrator to set or leave unchanged tolerances above negligible levels if there are special "benefits" associated with use of the pesticide. Significantly though, these bills all propose major changes in the nature of benefits considered in making risk-benefit balancing decisions.

The President's plan adds several new categories of benefits to the traditional concern -- economic impacts on producers.

In redefining the nature benefits, the Lugar and Rose bills propose incorporation of "relative risk" and "relative benefit" concepts in pesticide decision-making. Tolerances posing a health risk above a negligible level would be considered acceptable if the Administrator determines that consumers, farm-workers, or the environment would actually face greater risks, perhaps of another kind, if a given pesticide use were canceled. Such "relative risks" could arise from a natural contaminant in food posing a comparable or greater risk, as a result of a replacement pesticide leaching into groundwater or posing greater dietary risk, or the introduction of some new route of exposure in some area.

The debate over whether, in setting tolerances above an negligible risk level, to allow EPA to consider benefits (and the definition of "benefits" and how they will be measured) is one of the key unresolved issues facing the Congress. I urge the subcommittee to be very thorough in assessing whether:

* The definition of benefits can be defended before the general public

* There are agreed upon, credible methodologies to estimate the size of benefits and whether the data needed to do so is available without imposing another layer of expensive data requests on registrants, pesticide uses, commodity groups, or the government

* The switch to a new formulation of benefits will slow down the regulatory process and open up the EPA to a new decade-long adventure in the Courts trying to hammer out just what the Congress means in whatever new language is passed. ("Benefits", like beauty, is notoriously in the eyes of the beholder, and courts historically have had a hard time reading people's minds.)

Measurement of Exposure Important decisions have to be made by EPA in determining how to estimate dietary exposure to a particular pesticide that periodically appears in food. Three pieces of information are essential to make an estimation of exposure -- "who" is being protected (the average person, infants/children, the elderly), how much food that "who" consumes, and the average level of residues expected to appear in that food.

The four bills differ significantly in how they would direct EPA to carry out exposure assessments.

H.R. 3742, the Rose bill, includes specific language regarding how to estimate consumption -- "the 90th percentile of consumption of that food". An explanation of this term follows. Only 10 percent of all people ("all people" includes those who eat none of the food) would consume **more** than the individual at the "90th percentile" of consumers.

Note that this definition is different than the 90th percentile of **just** eaters, an alternative definition that results in a higher estimate of consumption since it excludes people who consumed none of the food in question. For common foods that most people eat, the distinction between the 90th percentile of eaters and the 90th percentile of everyone is not great; but for foods only some people consume at any given season during the year, like cherries or cucumbers, the distinction can be quite significant. For this reason, how FIFRA/FDCA reform legislation directs EPA to measure consumption is one of the **most significant** issues determining whether regulation will either provide relief for or

another hurdle ahead of minor uses.

A Digression

While clearly a very technical point, this difference between 90th percentile of eaters and 90th percentile of everyone is roughly comparable to **an order of magnitude** in estimated levels of consumption. Put simply, its just as important as changing the basic risk standard from one in one million to either one in one hundred thousand or one in ten million.

Accordingly, the authors of <u>all</u> bills pending before this subcommittee, the Administration, and anyone else coming forth with advice to this subcommittee on the topic of negligible risk should be prepared to explicitly clarify their own views and recommendations with respect to what **they** mean by "consumption." A lack of clarity and specificity in such essential matters has created troubles in the past. The reason many people do not trust risk assessment as a regulatory tool is because there are so many hidden assumptions and technical details that can be manipulated to produce unexpected results.

If the subcommittee does not want to fall into this same trap, you should be very clear and very explicit in the language that you pass. If you are not, I promise you that different people with different agendas will read into the language you pass what they want. A set of diverse expectations will be formed regarding what your proposed language **really** means, and what it will and will not do. I can promise one thing -- not everyone's interpretation will be right!!

Thus, without clarity you set the stage for some constituency to rise up later and say they were mislead. The Agency will face added difficulty in trying to decide what to do, and the stage will be set, once again, for litigation. Everybody loses.

No one knows what is "right" in the food safety area, and so it is understandable that this subcommittee might be reluctant to pass legislation that seems more definitive that the facts and our understanding will support. But our sad experience with pesticide regulation over the last 10 years or so convinces me that it is better to establish a clear, definitive, **provisional** body of law and regulation, and compel the EPA to get on with the task of living within the law. Sure, some decisions will be made that prove unwarranted; some products will stay on the market longer than they should have, but at least the program will be able to function more efficiently and expeditiously.

When and as new science and knowledge supports the need for changes in the **provisional** standards and definitions, either to a different **provisional** level or to some final formulation, then the Congress would be free to act and the Agency can get on with its

business. But no one's interest is served by this endless gridlock over basic, fundamental program elements, except of course the lawyers and lobbyists who play such an important role when agencies are trapped by a statute that too often can not distinguish between left and right.

The Rose bill specifies among the factors to be taken into account in setting tolerances "available information and reasonable assumptions concerning the variations in exposure levels and sensitivities of individual food consumers". This language, while far weaker than the Waxman-Kennedy mandate to set tolerances that protect infants and children, would allow EPA to alter its exposure and risk assessment procedures as it sees fit to take into account unique risks faced by special population sub-groups.

Factors to Incorporate in Risk Assessment Bruce-Bliley instructs EPA to proceed consistent with current policy and procedures -- using "average patterns" of food consumption among "average" people (standard EPA operating procedure is to base exposure assessments on an average weight adult), as well as actual measured residues.

The Waxman-Kennedy bill is again by far the most conservative of the 4 proposals. First, the bill calls upon EPA to set tolerances based on "probable consumption" within the age group that consumes the most of the individual foods on or in which a pesticide residue is expected to be found. In practice, this would probably translate into mean (average) consumption in the population group that consumes the greatest relative amount of a given food. For most foods consumed by infants and children, consumption will be greatest among the young.

Waxman-Kennedy also differs from the other proposals in that it requires the EPA to make exposure estimates assuming residues are at the tolerance level. This approach has been widely criticized within the food and agrichemical industries as a gross overestimate of actual residues, and hence actual exposure. The Waxman-Kennedy bill responds to this criticism by allowing exposure estimates to be based on actual residues, **but only if** EPA adjusts tolerances downward to equal the actual level of residues found in foods.

This provision, accordingly, provides a clear and strong inventive for tolerance reduction. Still, EPA could only reduce tolerances to the **highest** actual residue level it expects to find remaining on or in food from use of a pesticide across different regions of the country. For many pesticides, levels of residues vary greatly across geographic regions, in part because of how pesticides are used (different rates and numbers of applications, different formulations and pre-harvest intervals), and in part because of climatic differences.

For most pesticide uses, the provisions governing **measurement of exposure** in the Waxman-Kennedy will often result, when considered together, in between a one and two order of magnitude (10 to 100 fold) increase in estimates of exposure relative to the estimates that would result from the analogous provisions stipulated in the other three bills.

Estimation of Risk The last step in the risk assessment process is one of the most tenuous scientifically -- the translation of a given **measurement of exposure** into an estimated **level of risk.** This is done through use of various toxicological models developed to extrapolate the adverse health effect observed in laboratory animal experiments at various dose levels into estimated risks in humans at other, generally far lower dosage levels.

A key step in this process involves answering the question "Risks to whom?"

In most instances, regulatory scientists do not have access to risk assessment methods designed to account for the physiological differences across and among different population groups. Most scientists acknowledge pregnant women, infants, children, the aged, and the ill are likely to be more sensitive to exposure to certain chemicals, they really do not know how to empirically adjust currently available extrapolation models.

In the key area of oncogenic risks however, there is a consensus forming in the toxicological community that involves the calculation of annualized risks as a step toward a risk assessment methodology more sensitive to the unique risks faced by infants and children. An annualized risk is simple to calculate -- all that is needed is an exposure estimate for the year in question and the oncogenic potency factor, or Q*. To estimate annualized risk, the Q* is divided by 70, and then multiplied by the estimate of exposure. The number 70 is used because current oncogenic risk estimates are based on an assumption of a 70 year life-time of exposure.

These annualized risk extrapolations show that most children bear 40% to 60% of their total lifetime cancer risk from pesticides in the diet by the age of 10. Front-loading risk -- unless they are **truly** negligible -- like this makes no sense as a scientific proposition nor as a matter of public policy. Some scientists, and the Waxman-Kennedy bill, are advocating important changes in the definition and application of negligible risk in tolerance setting, in particular the promulgation of "child-adjusted tolerances".

A "child adjusted tolerance" would be set so that no infant or child faces more than **an annualized negligible risk** in any year of life. If this concept were passed as law, it would be a straightforward and simple exercise to calculate "child adjusted

tolerances" which would result in no more than one-seventieth of the agreed upon negligible risk level in any year of life.

Scientists and regulators are actively developing other novel risk assessment methods to help identify when a negligible risk level calculated for the general population would markedly exceed the level that would be needed to provide a comparable degree of protection to uniquely sensitive populations.

The President's plan is very clear in emphasizing that no changes would be made from current EPA risk extrapolation practices, which are, according to the agency, based on "generally accepted methods." The Bruce-Bliley bill basically requires the Administrator to continue using its current methods, but tempered through "reasonable" assumptions and methods. The intent is to discourage the Administrator from using risk extrapolation methods, data, or assumptions that artificially and inappropriately overestimate risks.

Compared to current EPA policy and risk assessment methods, and hence compared to the President's plan and the Bruce-Bliley bill, provisions in the Rose bill would provide EPA with authorization to exercise a higher degree of discretion and judgement in deciding the appropriate methods to estimate a given by the science in a specific case, of adopting risk extrapolation method that could result in estimated levels of risk **either** above or below those resulting from current EPA methods.

The Waxman-Kennedy bill, on the other hand, specifies that the Administrator must adopt risk assessment methods comparable to only the **most conservative** methods EPA currently uses. In other words, Waxman-Kennedy would compel EPA to use methods that, for some pesticides, would result in higher estimate of risk than EPA would make following current methods and policies. Waxman-Kennedy would also clearly prohibit, while the Rose bill would allow (but **not** mandate), risk assessment methods and assumptions that result in lower estimates of risk than the methods now commonly used by EPA.

An Overview of the Four Proposals It is difficult to characterize simply the combined consequences of the many differing provisions in the 4 major proposals discussed above. But in general, the Rose and Bruce-Bliley bills would provide EPA more flexibility than it now has to use judgement in deciding when and how the data on a particular pesticide should be used in determining whether risks from a given use of a pesticide exceed a negligible level. The Waxman-Kennedy bill is clearly more prescriptive that current law and policy, and would hence lessen the range of discretionary judgement the agency would be able to exercise.

Relative to current law and policy, the Waxman-Kennedy bill would almost certainly lead to significant risk reduction if

implemented as written; the Rose bill would probably lead to some reduction in risks, perhaps even more than under Waxman-Kennedy, **depending** on how the agency chooses to exercise its new authorities and discretionary options. The Bruce-Bliley bill clearly would allow the Administrator to develop a negligible risk policy which would result in little, if any reduction in risks, although like the Rose bill, the Administrator could still conceivably take actions that result in significant reductions of risk.

Mr. Chairman, I have gone on far too long already and in the interests of time, shall close. I look forward to answering any questions you might have.