S. HRG. 102-252

SAFETY OF PESTICIDES IN FOOD ACT OF 1991

HEARING

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

ON

S. 1074

TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO REVISE THE AUTHORITY UNDER THAT ACT TO REGULATE PESTICIDE CHEMICAL RESIDUES IN FOOD

JULY 10, 1991

Printed for the use of the Committee on Labor and Human Resources

U.S. GOVERNMENT PRINTING OFFICE
47-693 ⇆ WASHINGTON : 1991

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-035800-0

COMMITTEE ON LABOR AND HUMAN RESOURCES

EDWARD M. KENNEDY, Massachusetts, *Chairman*

CLAIBORNE PELL, Rhode Island
HOWARD M. METZENBAUM, Ohio
CHRISTOPHER J. DODD, Connecticut
PAUL SIMON, Illinois
TOM HARKIN, Iowa
BROCK ADAMS, Washington
BARBARA A. MIKULSKI, Maryland
JEFF BINGAMAN, New Mexico
PAUL D. WELLSTONE, Minnesota

ORRIN G. HATCH, Utah
NANCY LANDON KASSEBAUM, Kansas
JAMES M. JEFFORDS, Vermont
DAN COATS, Indiana
STROM THURMOND, South Carolina
DAVE DURENBERGER, Minnesota
THAD COCHRAN, Mississippi

NICK LITTLEFIELD, *Staff Director and Chief Counsel*
KRISTINE A. IVERSON, *Minority Staff Director*

CONTENTS

STATEMENTS

WEDNESDAY, JULY 10, 1991

ADDITIONAL MATERIAL

SAFETY OF PESTICIDES IN FOOD ACT OF 1991

WEDNESDAY, JULY 10, 1991

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 10:12 a.m., in room SD-430, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Dodd, Simon, Hatch, Kassebaum, and Cochran.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. The committee will come to order.

Today's hearing addresses the safety of the Nation's food supply. The measure before us, the Safety of Pesticides in Food Act of 1991, would institute long overdue reforms in the Federal regulation of pesticide residues. These reforms are designed to provide a greater protection for the public, especially children, from the hazards of pesticides.

The Federal Government has not been doing an adequate job of protection in this area, and the American people know it. It is unsatisfactory that families cannot receive a definitive response that the food on their tables is safe. The debate over pesticides can easily become a sea of numbers, confusing to Congress and citizens alike. What we need is a credible system to regulate pesticides, and we need it soon.

Under current Federal regulations, residues from over 300 pesticides are permissible on the food we eat. Up to 25 percent may cause cancer in animals. What does this mean for human health? We don't know—and that is the problem.

Two basic principles underlie this legislation. The public has a right to demand of chemical manufacturers, the food industry, and Government: If you don't know what the health risks of a pesticide are, find out. Once you determine that the risk is substantial, take the product off the market.

In 1976 I sat on the Judiciary Committee's Subcommittee on Administrative Practice and Procedure, which issued a report detailing the inadequate health and safety database for pesticides. Now, 15 years later, we still have serious doubts about which pesticides are safe and which are not. It is unacceptable when it takes decades—not years—to resolve basic questions about food safety.

The bill I have introduced establishes a standard specifying that pesticide residues on food cannot exceed levels that contain more than a "negligible risk" of causing adverse human health effects.

An important provision of the bill establishes a mechanism to assure that infants and children up to the age of 5 are not exposed to more than a negligible risk from pesticides. Over the 4th of July recess, I noticed that many of my young relatives were eating large numbers of apples and bananas, and I wondered whether they were consuming residues that might harm them. I want to be sure that our regulatory system protects the safety of all children.

Because of their food consumption patterns and low body weights, children can receive a disproportionate share of lifetime cancer risk from a pesticide at an early age. Also, since latency periods are so crucial in determining cancer risk, exposures in children pose the greatest potential harm. This bill will prevent the unacceptable front-end-loading of risk.

There are also concerns about other toxic effects of pesticides. As the American Academy of Pediatrics noted in expressing its support for a "children's standard", the tissues and organs of young children under 5 are "exquisitely sensitive" to toxins, and exposure in early years can cause permanent and serious health effects. We cannot consider the food supply to be truly safe unless we are confident that it is safe for infants and children too, and this bill will take a major step toward that goal.

The bill also requires timely decisions about pesticide tolerances, and tolerance decisions must be supported by scientifically sound data. By simplifying the procedures for removing unsafe pesticides, the legislation ensures that the status quo will no longer favor pesticides for which there is incomplete or unreliable data.

The restoration of public confidence in the food supply will serve the interests of farmers, the food industry and chemical manufacturers as well as consumers. Everyone loses when we face intermittent panics which do nothing more than show the failure of our current system and the mistrust of the public in Government's claim that there is no need to worry.

The need for action is obvious, and it is up to Congress and the administration to respond.

Senator Hatch.

Opening Statement of Senator Hatch

Senator Hatch. Thank you, Mr. Chairman.

I am pleased that we are continuing our discussions on the need to revise our Nation's food safety laws, and I look forward to the testimony of these witnesses here today.

For over a decade I have sought changes in the food safety laws, and I think we have to be aggressive in resolving any conflicts among consumers, producers, processors, etc.

During the last session of Congress, there were fruitful discussions. The Bush Administration proposed meaningful and good legislative policies to revise the Federal Food, Drug and Cosmetic Act. Senator Kennedy and I participated in these discussions, and we nearly formulated a bipartisan agreement. I hope that this Congress will finally be able to forge a bill.

If I could craft a bill to change the food safety laws, I believe that we must start at the basics. The American consumers want to know that their food supply is safe. I believe there are two pillars that must be constructed to restore consumer confidence.

First, we must establish a strict and uniform food safety standard that is based on sound science, the best available science, in ensuring that our products only pose a negligible risk of harm.

Our current law, which utilizes a "zero risk" standard, is no longer scientifically feasible. Further, this Delaney paradox is working to keep safer products off the market which could replace older, less safe products. Every Commissioner of the Food and Drug Administration for the past 29 years has called on Congress to remove the rigidity of the Delaney clause. The current Commissioner, David Kessler, has already shown his commitment to a safe and reliable food policy for this country with his actions on any possible mislabeling of food products.

These past commissioners are scientists, appointed by presidents of both parties, who recognize that we must have workable, scientifically accurate Federal laws in order to protect the safety and health of American consumers.

The second pillar we must construct is to pass stronger enforcement laws that allow the removal of unsafe products with prudent dispatch. Our current system requires a process which takes four to 8 years before a product can be suspended or canceled for use. That is too long, and it is not surprising that States are now undertaking efforts to protect their citizens because our Federal laws are so erratic. Rather, we need a strict and uniform safety standard with strong enforcement tools so that we protect citizens in Utah as well as the citizens in Massachusetts or any other State.

I recognize that there will be give and take. And I want to participate in those discussions, and I am prepared to resolve them. And, after we complete our action we will need to involve the Agriculture Committee in resolving the FIFRA modifications.

I urge you, Mr. Chairman, to resume these negotiations because there is no more important consumer need than ensuring our food safety laws provide adequate protection for Americans.

Again, I look forward to the testimony of the witnesses today, and I urge my fellow members of the committee to listen to the men and women who have come before us today. I think that we will hear a clear message that science has taken us to a new realm and that we must abandon the "zero risk" standard for one of more reasonable application.

I thank you for holding these hearings and appreciate the leadership you have provided in this area.

The CHAIRMAN. Thank you. I certainly want to underscore what Senator Hatch has mentioned. We worked closely together during the last Congress with the administration, and I think that if we hadn't had the rush of the adjournment there was a good possibility that we might have made some important progress. I am not quite sure we would have met all of our responsibilities, particularly with regard to the children's issues that have emerged into greater profile. Still, we certainly look forward to working with all the members of the committee this Congress.

Senator Simon.

OPENING STATEMENT OF SENATOR SIMON

Senator SIMON. Thank you, Mr. Chairman. I want to join Senator Hatch in commending you, and I also want to join you in commending Senator Hatch. The two of you have provided solid leadership in this area, and I think it is extremely important.

We clearly have to do a better job. We are doing a better job than we were decades ago, but we have to do a still better job, in protecting the safety of our food and in restoring public confidence.

I am particularly pleased that the legislation hits on the aspect of children and that our testimony today will do that.

I'm not sure whether we are going to get into the other areas of concern that I have, and whether this is the vehicle for them, but I am concerned about a couple of other things. I visited a migrant camp over the 4th of July recess and was told about migrant workers getting sick from pesticides. We have to protect them. But the very pesticides that can make migrant workers sick—what does that do to the people who consume these foods?

I don't know the answer. Maybe there is no relationship—but maybe there is.

I am also concerned that we permit the exportation of pesticides that we do not permit farmers to use here in our country. Why should we permit pesticides to be sent to Mexico or Chile or any other country if we say they are not safe for the people of the United States?

And in that connection, how do we then protect the safety of food that we bring in from Mexico or Chile, or other countries? I remember taking up with the former head of the FDA the whole question of safety of imported food,, who said that we just don't have the resources to provide even token protection for the American public.

I think we do need some strengthening of the laws in this area, or at least some improvement of how we enforce the present laws.

But these are areas that I assume we can get into during the testimony. Mr. Chairman, I thank you for once again providing solid leadership in an area to protect the public.

The CHAIRMAN. Thank you very much, Senator Simon.

For our first panel, we are pleased to have Professor John Wargo from the Yale School of Forestry and Environmental Studies, as well as Richard Jackson, chairman of the American Academy of Pediatrics Committee on Environmental Health.

Professor Wargo, welcome.

STATEMENTS OF JOHN P. WARGO, PROFESSOR OF PUBLIC POLICY AND ENVIRONMENTAL STUDIES, YALE UNIVERSITY, NEW HAVEN, CT; AND DR. RICHARD J. JACKSON, CHAIRMAN, AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON ENVIRONMENTAL HAZARDS, SACRAMENTO, CA

Mr. WARGO. Thank you, Senator Kennedy.

I am honored to appear before you today to discuss the merits of proposed changes in legislation. I am appearing today as a faculty member at Yale University, where I hold appointments in the school of forestry and environmental studies, the political science

department, and where I am director of undergraduate studies for Yale College's New Studies in the Environment Program.

My appearance today is conditioned by several important reservations. I have been working with the National Academy of Sciences Committee on Pesticides in the Diets of Infants and Children, which has been charged by Congress and EPA with the task of determining if children are sufficiently protected from potentially harmful exposures to pesticides by current law. In an ideal world, Senator, the committee's conclusions and recommendations would be available for presentation today. Obviously, this is not the case.

The comments I am making today reflect only my own opinions. I am not a spokesperson for the committee. Also, I must refrain from divulging findings, conclusions and recommendations of this committee, which may make it in the future necessary for me to decline to respond to certain specific questions. And if I sense a conflict between the question and the possibility of disclosing these findings, I hope you will understand.

The CHAIRMAN. We appreciate that. There are many important areas of public policy that are being addressed by the National Academy of Sciences, and all of us value very much the conclusions the academy will reach. But, many of those individuals who are most knowledgeable are on various panels, and we have a responsibility in terms of the timeliness of public policy questions. So we certainly respect your position, but we know that your knowledge as well as Dr. Jackson's has been built upon a long lifetime of concern for these issues, and that's really what we are interested in drawing upon here.

Mr. WARGO. Thank you. The data that I am going to present today is actually data that was compiled before the National Academy of Sciences committee was put together, and as you have suggested, I have been working in this area for nearly a decade.

If you carefully look at the 1977 and 1978 food consumption survey developed by the Department of Agriculture, and you break that survey down, looking at food consumption patterns by children and compare them to adults, some rather striking results occur.

Kids have a much lower level of dietary diversity than adults do. They simply eat fewer foods, and therefore they eat more of those fewer foods. They eat more; their consumption is higher per unit of body weight than for adults for fruits and vegetables in particular—apple juice, orange juice, milk products, apples, peaches, pears, plums and bananas.

In fact, if you look at the first chart on your right, you will see a simple graph of consumption of apple juice over different age periods. The "x" axis shows us ages one, 2, 3, on up through 20, and at the end you see U.S. average consumption. You see that the zero-to-1 year-old consumes 3.3 grams per kilogram body weight per day of apple juice, compared to the 20 year-old, who consumes about .3.

So there is a substantial difference in the intake of foods, particularly fruits and vegetables, as well as liquids.

Another important point here is that no one eats an average amount of food. And EPA, in their exposure estimation process, when they try to figure out how many chemicals we are exposed to

and at what levels, particularly for chronic cancer risk assessment, would presume an average intake value over a 70-year period.

No one, from the data that I have looked at, eats an average amount of every food. In fact, people eat higher amounts of fewer foods.

There are several substantial limitations to the consumption data that we have available to us today to estimate exposure. The current consumption data set is a three-day survey conducted in 1977 and 1978. So right off the bat, you understand that this survey data is now 13 or 14 years old. And with the changes in food technology, changes in marketing techniques, changes in simply taste, you find rather dramatic differences across time.

Another limitation is that we're not tracking individuals' consumption patterns over time. So we are not tracking "Jane Doe" from age one to age 10, so we don't really know how that individual's consumption is changing. Instead, we do a one-time survey, say in 1978, and then we look at individual age classes and then attempt to project out over long periods of time what the risk might be.

Now, remember that the tradition in cancer risk assessment is to project risks out over a 70-year period. My argument is that we certainly don't want to use data that is that old to protect our risks over such a long period of time. Part of my expertise lies in the area of computer modelling, and one of the maxims of computer modelling is that you don't model or forecast into the future further than your data would permit, or looking back too far at the data trying to project too far into the future what the risk might be. This is a serious problem.

Let me mention several residue issues. In my mind, of the three major components of the risk equation—consumption data, residue data and toxicity data—the consumption data is in the best shape; residue data is not in good shape. The limitations are primarily related to the fact that FDA collects data for the purposes of monitoring and enforcement—not for the purposes of exposure assessment. So that the sample, the survey design, is not statistically appropriate for estimating exposure of the general population to pesticides, let alone exposure of small children to pesticides.

We have very little knowledge about distribution of foods, tracking where they are grown, what pesticides are used on them, and where they end up. Also, EPA is constantly struggling under budgetary constraints in their attempts to figure out what happens to a residue when it moves from a raw food such as apples to a processed food form on apple juice. They often require detailed tests to be able to tell them whether or not the residue values are concentrating or diminishing.

The data sets are also plagued by small sample sizes. If you take a look at the 300 foods, Senator, that you mentioned—or, 300 chemicals on, say, 376 different foods—you find that for a single chemical on a single food, often the sample size of residue is far too small to be able to project back exposure estimates on the entire population.

I am going to let my colleague, Dick Jackson, talk about toxicity issues in the interest of time.

The basic reason this committee has convened here today is to try to come to a conclusion about whether or not the current standard is reasonable. Is the Delaney amendment, the zero risk standard, a reasonable way to approach this problem?

My argument is that, no, it is not, and let me offer you several options as potential solutions.

You could set a health-based standard, an acceptable level of risk, and it has become a term of art or a tradition in Washington now to talk about a 10 to the minus 6th risk or a one in a million risk. That presumes that a person is exposed for an entire lifetime. Their chance would increase by one in one million of gaining a tumor at some point during that period.

Well, where do you want to set this standard? This is a critical question. Do you want to set this standard based on a single chemical and a single food—say, alar in apple juice, or benamil on tomatoes. If you do that, you are going to allow risk to build up across all of the chemical food combinations that exist in the system. If you go to the Code of Federal Regulations, and you look at how many chemical food tolerances are on the book, the last time I checked it was 8,843. So are you going to allow a 10 to the minus 6th risk to accumulate over 8,843 different cases? My argument is no, and nobody is arguing that that should be the case.

Option number two is to set that standard, 10 to the minus 6th, per chemical, and say that all of the uses of benamil or aldicarb—not aldicarb; it's not an oncogen—benamil or, say, alar should not result in a total risk greater than 10 to the minus 6th. In fact, that is commonly thought to be a very reasonable solution to this problem.

However, remember again there are 320-odd food use chemicals that are permitted for use in the food supply, and if you define the standard as 10 to the minus 6th or one in one million per chemical, then you basically are not regulating how that might accumulate across the entire diet, which I think is a very important point.

In my mind, if I were going to design a vision for where our food supply risk level ought to be set, I would say a 10 to the minus 6th standard over the entire diet. Now, obviously, I'm surprised tomatoes are not hitting me in the back of the head, but in my view, no one is interested in having an increased incidence of cancer risk from a pesticide in the diet.

I teach 250-300 students per year, so say over the last decade I have taught several thousand students, and I teach pesticide regulation, and I teach exposure modelling, and I have consistently asked those students whether or not they are willing to assume an increase in cancer risk. And they don't want to if they have an option, particularly if it is a no-cost option.

So the basic question is this: How much cancer risk should the U.S. population bear without its consent? And this is a very delicate issue since one group is reaping the benefits while the entire population is bearing the risks. And the question here today that we are confronting directly is are children bearing a higher risk than we think is reasonable.

EPA will tell you that these are technical matters and that they should be handled administratively. My argument to you is that these are not technical matters. The establishment of a risk stand-

ard at 10 to the minus 6th by food, by the diet, or by chemical is inherently a political issue. It is something that I think this committee is well-positioned to take on.

Let me apprise you of several recent findings that you have in charts behind you. If you look at the dietary differences, you find in Chart 1—again, let me just refresh your memory—children are consuming more as 1 year-olds than they are as 5 year-olds, and by the time they approach the age of 20 they are consuming a much lower level of apple juice. If I put up a chart of orange juice, peaches, pears, the chart would look quite similar.

If you then factor in residue data, actual market basket residue data as well as cancer potency factors, to develop a risk estimate, you have the results in Chart 2, the middle chart. What I have done here is simply to annualize the risk so that the risk is being presented year by year.

The message here from the middle chart is that kids are accumulating risk at a more rapid rate than one would assume if one looked at the U.S. average level. The U.S. average amount of risk is demonstrated on the far right-hand side of the middle chart.

The far right chart demonstrates the proportion of lifetime risk that is accumulated in different age periods. Again, the "x" axis is simply ages. So that you see for 1 year-olds, they had been accumulating according to EPA's estimates approximately 36 percent of lifetime cancer risk while alar was permitted for use. And my understanding is that its tolerances have now been completely canceled as of May 31, 1991. So this is not a problem today, and I am choosing this example because this is an example that the National Academy of Sciences is not choosing, but it demonstrates very clearly that a 10 to the minus 6th risk can be accumulated for one chemical on one food for 1 year in life, and that this rate of accumulation is something that needs to be regulated. And I think that the standard that has been proposed in your legislation of allowing a 10 to the minus 6th risk per chemical, but not permitting its rate of accumulation for any age class, ages one to 5, to exceed 10 to the minus 6th divided by 70 would be a very protective device.

Let me briefly conclude my testimony by saying that what is clearly at stake here is the credibility of the entire regulatory system. We had the merits of using alar being debated on the Phil Donahue show and on "60 Minutes" rather than within EPA hearing rooms. This demonstrates to me system failure.

Loss of public trust in regulators charged with protecting our food supply is a very dangerous situation, and it is my belief that a clear, protective health-based standard such as the one that you have proposed would restore that public trust.

Thank you very much.

[The prepared statement of Mr. Wargo follows:]

Prepared Statement of Mr. Wargo

I. INTRODUCTION

Thank you Senator Kennedy. I am honored to appear before you today to discuss the merits of proposed changes to the FIFRA and FFDCA. As you are aware, I have spent the past 7 years researching childhood patterns of food consumption and associated pesticide exposure, as a basis for evaluating the safety of the nation's food supply. My academic expertise lies in the area of public policy. Particularly, I study how scientific uncertainty is exploited by special interests in the setting of regulatory policy.

I should also tell you that I have been as critical of environmental and consumer groups as I have of private corporations in their methods of data analysis and interpretation of results. My "special interest" is simply the environmental health of children.

I am appearing here today as a faculty member at Yale University, where I hold appointments in the School of Forestry and Environmental Studies, the Political Science Department and where I am Director of Undergraduate Studies for Yale College's Studies in the Environment Program. My appearance is conditioned by several important reservations. I have been working with a National Academy of Sciences Committee on Pesticides in the Diets of Infants and Children, which has been charged by Congress and EPA with the task of determining if children are sufficiently protected from potentially harmful exposures to pesticides by current law. In an ideal world, the Committee's conclusions and recommendations would be available for presentation at this hearing. Obviously this is not the case.

The comments I am making today reflect only my own opinions and interpretations, not those of the NAS Committee. I am not appearing as a spokesperson for the Committee. Also, I must refrain from divulging findings, conclusions and recommendations of the Committee, which may make it necessary for me to decline to respond to certain specific questions. If I sense a conflict and decline to respond, please understand that it is my respect for scientific process including full and fair peer review of the Committee analyses which is the cause. It is my understanding from conversations with your staff that such a response would be acceptable.

Also, all of the data which I am presenting is available to the public. The food consumption data has been available now for nearly 13 years.

I have been a student of pesticide policy for eight years, having taught both undergraduate and graduate courses in pesticide regulation and computer modelling at Yale and before that at Dartmouth College. My knowledge of childhood patterns of food consumption, and the implications for pesticide exposure and regulation, predates the NAS Committee's formation by at least five years.

II. AGE RELATED VARIANCE IN FOOD CONSUMPTION

If one looks at Table B-2 on page 192 of the Delaney Paradox study published by the National Academy Press, you will find a table prepared by me in 1987 demonstrating differences in patterns of food consumption if childhood and US average intake are compared. There is an interesting footnote to that table, which suggests one reason why we are all here today. It reads:

> "Differences in mean consumption estimates among subpopulations will result in differences in chemical intake estimates."

Only a brief acquaintance with food consumption data sets makes it obvious that consumption patterns vary significantly with age, region of the country, ethnicity and income levels. The idea that there is a stable pattern of food consumption which would permit the estimation of risk across 70 years is patently ridiculous.

The following tables summarize age related variance in patterns of food consumption derived from the 1977-78 National Food Consumption Survey. These data were published by me along with Daniel Krewski, Chief of Biostatistics at Health and Welfare, Canada and Robert Rizek, of the Human Nutrition and Information Service, USDA.

Two different research strategies were then employed. First, for each age class, the data were arrayed from most consumed to least consumed food, by percentage of the total diet. The consumption estimate for each age class and food type was then compared to the entire sample to estimate a multiple of U.S. average consumption, again for each food. These data are arrayed in the tables which appear at the end of this article. Significant findings for each age class are described briefly below.

TABLE 1
FOODS REPRESENTING GREATER THAN 1% OF US AVERAGE DIET ('77-78)
AND AGE CLASS CONSUMING HIGHEST MULTIPLE ABOVE US AVERAGE CONSUMPTION

	COMMODITY DIET	% US AVG CONSUMING OF US AVERAGE	AGE CLASS HIGHEST MULTIPLE	MULTIPLE OF US AVG CONSUMPTION
1	WHEAT-FLOUR	0.074	CHILDREN 1-6	2.25
2	BEEF-LEAN	0.069	CHILDREN 1-6	1.82
3	ORANGES-JUIC	0.067	CHILDREN 1-6	3.08
4	MILK-NON-FAT	0.054	NON-NURSING INFANTS	7.33
5	POTATO(WH)-P	0.047	CHILDREN 1-6	2.14
6	CANE SUGAR	0.044	CHILDREN 1-6	2.49
7	EGGS-WHOLE	0.033	CHILDREN 1-6	2.30
8	TOMATOES-WHO	0.029	CHILDREN 1-6	1.68
9	APPLES-FRESH	0.028	NON-NURSING INFANTS	6.91
10	MILK-FAT SOL	0.025	NON-NURSING INFANTS	3.62
11	PORK-LEAN	0.023	CHILDREN 1-6	1.84
12	CHICKEN+SKIN	0.023	CHILDREN 1-6	2.15
13	BEEF-FAT	0.022	CHILDREN 1-6	1.81
14	POTATO(WH)-W	0.021	CHILDREN 1-6	1.79
15	BEET SUGAR	0.019	CHILDREN 1-6	2.49
16	SOYBEANS-OIL	0.019	NON-NURSING INFANTS	4.55
17	APPLES-JUICE	0.014	NON-NURSING INFANTS	16.65
18	CORN,SWEET	0.014	CHILDREN 1-6	2.39
19	BANANAS-FRES	0.014	NON-NURSING INFANTS	4.96
20	PEACHES-FRES	0.013	NON-NURSING INFANTS	10.60
21	LETTUCE-HEAD	0.013	NURSING FEM 13+	1.57
22	PORK-FAT	0.012	CHILDREN 1-6	2.10
23	BEANS-SUCC-G	0.012	NON-NURSING INFANTS	4.05
24	FISH,FIN-SAL	0.011	NURSING FEM 13+	2.41
25	PEAS SUCC-GA	0.010	NON-NURSING INFANTS	3.72
26	CARROTS	0.010	NON-NURSING INFANTS	9.05
27	TOMATOES-PUR	0.010	CHILDREN 1-6	2.15
28	CORN,GRAIN-E	0.010	HISPANICS	3.37
29	RICE-MILLED	0.010	NON-NURSING INFANTS	8.69

TABLE 2
NURSING INFANTS
FOODS CONSTITUTING HIGHEST PERCENTAGES OF DIET
1977-1978

(n=109)

	FOOD TYPE	% DIET	MULTIPLE OF US AVERAGE
1	APPLES-JUICE	0.119	14.9
2	APPLES-FRESH	0.097	6.3
3	ORANGES-JUICE	0.063	1.7
4	PEARS-FRESH	0.061	14.4
5	MILK-NON-FAT SOL	0.059	2.0
6	PEACHES-FRESH	0.057	7.7
7	CARROTS	0.046	7.9
8	BEEF-LEAN	0.043	1.1
9	MILK SUG (LACT)	0.039	27.9
10	BANANAS-FRESH	0.037	4.8
11	RICE-MILLED	0.025	4.7
12	PEAS SUCC-GARDEN	0.018	3.1
13	BEANS-SUCC-GREEN	0.018	2.6
14	OATS	0.016	5.9
15	SOYBEANS-OIL	0.015	1.5

TABLE 3
NON-NURSING INFANTS
FOODS CONSTITUTING MORE THAN 1% OF AVERAGE DIET

	FOOD TYPE	% DIET	MULTIPLE OF US AVERAGE
1	MILK-NON-FAT SOLIDS	0.123	7.3
2	APPLES-JUICE	0.075	16.7
3	MILK SUG (LACT)	0.063	79.1
4	APPLES-FRESH	0.060	6.9
5	ORANGES-JUICE	0.059	2.9
6	PEACHES-FRESH	0.044	10.6
7	PEARS-FRESH	0.036	15.0
8	CARROTS	0.029	9.1
9	MILK-FAT SOLIDS	0.029	3.6
10	BEEF-LEAN	0.028	1.3
11	SOYBEANS-OIL	0.027	4.6
12	RICE-MILLED	0.027	8.7
13	COCONUT-OIL	0.025	49.8
14	BANANAS-FRESH	0.021	5.0
15	WHEAT FLOUR	0.018	.8

TABLE 4
CHILDREN 1-6
(n=3,663)

FOODS CONSITITUTING THE HIGHEST PERCENTAGE OF DIET AND MULTIPLE ABOVE US AVERAGE CONSUMPTION ESTIMATE

	FOOD TYPE	% DIET	MULTIPLE OF US AVERAGE
1	ORANGES-JUICE	0.091	3.1
2	WHEAT-FLOUR	0.074	2.3
3	MILK-NON-FAT SOLIDS	0.072	3.0
4	BEEF-LEAN	0.056	1.8
5	CANE SUGAR	0.048	2.5
6	POTATO(WH)-PULP	0.045	2.1
7	APPLES-FRESH	0.035	2.8
8	EGGS-WHOLE	0.034	2.3
9	MILK-FAT SOLIDS	0.032	2.8
10	APPLES-JUICE	0.030	4.8
11	CHICKEN+SKIN	0.022	2.2
12	TOMATOES-WHOLE	0.022	1.7
13	BEET SUGAR	0.022	2.5
14	BANANAS-FRESH	0.020	3.3
15	PORK-LEAN	0.019	1.8

TABLE 5
CHILDREN 7-12
FOOD CONSUMPTION BY PERCENT OF AVERAGE DIET 1977-78

	FOOD TYPE	% DIET	MULTIPLE OF US AVERAGE
1	WHEAT-FLOUR	0.085	1.7
2	ORANGES-JUICE	0.072	1.6
3	BEEF-LEAN	0.067	1.4
4	MILK-NON-FAT SOL	0.066	1.8
5	POTATO(WH)-PULP	0.052	1.6
6	CANE SUGAR	0.052	1.7
7	APPLES-FRESH	0.032	1.7
8	MILK-FAT SOLIDS	0.031	1.8
9	EGGS-WHOLE	0.028	1.2
10	TOMATOES-WHOLE	0.026	1.3
11	BEET SUGAR	0.023	1.7
12	CHICKEN+SKIN	0.021	1.4
13	BEEF-FAT	0.021	1.4
14	PORK-LEAN	0.020	1.3
15	SOYBEANS-OIL	0.019	1.5

TABLE 6
TEENAGERS AGES 13-19
FOOD CONSUMPTION BY PERCENT OF AVERAGE DIET 1977-78

FOOD TYPE	% DIET	MULTIPLE OF US AVERAGE
WHEAT-FLOUR	0.086	1.07
BEEF-LEAN	0.077	1.03
ORANGES-JUICE	0.063	0.87
POTATO(WH)-PULP	0.057	1.10
MILK-NON-FATSOL	0.056	0.97
CANE SUGAR	0.052	1.10
EGGS-WHOLE	0.031	0.87
TOMATOES-WHOLE	0.030	0.96
MILK-FATSOLIDS	0.028	1.01
PORK-LEAN	0.025	1.01
BEEF-FAT	0.024	1.04
APPLES-FRESH	0.024	0.79
CHICKEN+SKIN	0.024	0.95
BEETSUGAR	0.023	1.10
POTATO(WH)-WHOLE	0.020	0.92

TABLE 7
ADULTS: 20 YEARS AND OLDER
FOOD CONSUMPTION BY PERCENT OF AVERAGE DIET 1977-78

FOOD TYPE	% DIET	MULTIPLE OF US AVERAGE
BEEF LEAN	0.076	0.83
WHEAT-FLOUR	0.070	0.71
ORANGES-JUICE	0.055	0.61
POTATO(WH)-PULP	0.047	0.74
CANE SUGAR	0.037	0.64
EGGS-WHOLE	0.037	0.83
TOMATOES-WHOLE	0.034	0.88
MILK-NON-FATSOL	0.033	0.47
PORK-LEAN	0.027	0.87
POTATO(WH)-WHOLE	0.025	0.90
BEEF-FAT	0.024	0.83
CHICKEN+SKIN	0.024	0.79
APPLES-FRESH	0.021	0.58
MILK-FATSOLIDS	0.019	0.57
SOYBEANS-OIL	0.019	0.75

Since EPA currently is using the 1977-78 NFCII data as a basis for exposure and risk assessment I initially explored variance among the age classes which they employ. This survey has numerous deficiencies including its age, the fact that it was conducted only over one three-day period, and the small sample size of the nursing infant age class. Perhaps the most important limitation is the fact that the survey reflects consumption patterns for only a single slice in time, while it is likely that dietary patterns change with considerable speed. Also, there is little reason to believe that one three-day period is an accurate reflection of either long-term consumption patterns which might be used for chronic exposure and risk assessment, or short-term single-day high consumption levels which might be used for acute exposure and risk assessment. Still, this survey constitutes the most comprehensive data set currently available to compare all age classes in our population.

Individual consumption reports were broken into 376 different types of foods and 691 forms of those foods. Average consumption was calculated for 376 different types of food, and for 22 different population subgroups, and then aggregated into five age classes including non-nursing infants, children 1-6, children, 7-12, teenagers and adults over 20. Food consumption patterns have also been aggregated yearly between the ages of birth and 20, however the aggregation just described was performed to make comparisons possible between these analyses and analyses commonly performed by EPA using their tolerance assessment process.

Twenty-two foods constitute more than 1% of the average non-nursing infant's diet. Six of these are fruits which together account for 29% of the diet while nine foods are fruits or vegetables making up 37% of the diet. Soy and coconut oil together account for 5.2% of the diet, most likely from infant formulae. Non-nursing infant consumption of soy oil is 4.6 times higher than the U.S. average level, while coconut consumption is 50 times the U.S. average, a fact which could have significant implications for the regulation of fat soluble pesticides. Milk products consititute 21.5% of the average non-nursing infant's diet, 7.3 times the U.S. average for non-fat milk solids intake and 3.6 times the U.S. average for fat milk solids. Of the 376 foods surveyed, only 148 were positively reported as consumed for non-nursing infants while 375 were reported for the entire 30,770 person sample, indicating a relatively low level of dietary diversity. These data immediately suggest the importance of monitoring both the percentage of total diet and the multiple of the U.S. average consumption level as critical indicators of concern for estimating dietary exposure to pesticides. It is important to recall that for the overwhelming majority of tolerances currently in effect, exposure and risk estimates related to tolerance are founded upon U.S. mean food consumption levels by food type.

Children between the ages of 1 and 6 consume 26 different foods which individually account for more than 1% of their diet. Seven of these are fruits or fruit juices totalling 21% of the diet. For once it may be appropriate to compare apples and oranges since together they constitute 16% of the diet. Dietary diversity has increased in this age class through the increased dominance of wheat, beef, sugar, eggs and chicken and increased variety of vegetable consumption. The number of foods consumed above the U.S. average level has declined, as have the magnitudes of the multiples above average levels. This is likely a response to two variables: first, a rapid increase in dietary diversity after the age of 1, and second, a diminishing effect of the bodyweight conversion factor as average childhood weights approach average adult weights.

Children between the ages of 7 and 12 have even a greater level of dietary diversity and diminishing dominance of any single food. Wheat flour, beef, and potatoes constitute a higher percentage of the diet, while orange juice and apple products have fallen, though only slightly. The 15 most consumed foods for children 1-6 and those 7-12 are almost identical, although the relative rankings differ slightly. The average intake for children 7-12 approaches the U.S. average intake.

For teenagers (13-19 years old) wheat flour, beef, potatoes and eggs, continue their ascendance in relative importance over fruits and vegetables with the exceptions of orange juice (which is still among the three most consumed foods, and tomatoes. Again, dietary diversity expands with age while the consumption estimates, when expressed as multiples above U.S. average levels, continue to decline with age. Also, for the first time, 7 of the top 10 foods are consumed at a level less than the U.S. average.

Adult food consumption patterns reflect a continuation of the trends noted above. Beef becomes the most consumed food, while intake of wheat flour, orange juice, potatos and milk decline slightly from teenage levels. The list of the 15 most consumed foods is almost identical for both teenagers and adults; and diversity of foods increases again with age, although this may be the result of the large adult sample size. Similarly, the level of adult food intake is extremely close to the U.S. average estimate.

A closer examination of the consumption patterns of children less than 12 years of age reveals that for each of the 15 most consumed foods, childhood intake is higher than adult intake and U.S. average intake, demonstrated by Table 1. This finding raises a serious question concerning the selection of the most appropriate food consumption level to use as a basis for estimating pesticide exposure. Choice of the U.S. average consumption level may dramatically underestimate food consumption and associated pesticide exposure for children.

Nearly 45% of nursing infants'diet is composed of fruit products. Six of the ten most consumed foods are fruits constituting 43% of the average diet. Nursing infants consume over five times the U.S. average consumption level for 22 different commodities. Half of these foods are either fruits or vegetables which collectively represent over 44% of the average nursing infant diet.

III. RESIDUE DATA

Similarly, there is tremendous variance among sources of residue data: field trial, warehouse, marketbasket, domestic, import, compliance and surveillance residue surveys are likely to yield quite variable results. This variance is often significant within a year, let alone across a 70 year period. Chemical use patterns may also vary substantially from one year to the next, and from one region of the country to another, making the projection of a 70 year pattern of exposure and associated risk equally absurd.

IV. RISK ESTIMATION

To understand the reasonableness of various risk standards, one needs briefly to consider how risks are calculated. This is a very simple piece of algebra. The amount of food consumed is multiplied by the expected residue value and the product is an exposure estimate. Thus if you ate one kilogram of apples (obviously an exaggeration), and there was 1 mg of chemical X per kilogram of apples (1 ppm) then your exposure would be the product, or 1 mg of chemical X. This exposure would then be adjusted based upon your bodyweight and expressed as Y mg/kg bw/day.

The resulting exposure, adjusted by safety factors, may then be compared with acceptable daily intake levels derived from toxicity studies or it may be translated into an estimate of cancer risk. The cancer risk estimate is derived by multiplying the exposure by a "cancer potency factor" which is simply an estimate of the expected number of tumors associated with any given exposure. So if one knows the exposure to Chemical X, and the cancer potency of Chemical X, then one can multiply the two to yield an estimate of expected cancer risk.

V. NEGLIGIBLE RISK STANDARD

The tradition in cancer risk assessment has been to presume consistent exposure across a lifetime to yield a lifetime risk estimate. This estimate is commonly expressed as "one tumor in one million people exposed at dose x over 70 years, or an average lifetime." Not only does this approach assume consistency in food consumption, but also consistency in chemical residue levels on the dinner plate.

In the area of cancer risk assessment, the level of complexity is similarly enormous. Variance in risk estimates may be due to differences in physiological susceptibility, food consumption patterns, residue levels in food, and variance in toxicity studies.

The appropriate public policy response to this variance seems quite simple.

1. Use the best available data.
2. Characterize the uncertainty in the data accurately.
3. Characterize the variance in exposure and risk among groups which are physiologically most sensitive to the toxins.
4. Choose a time horizon that the data supports.
5. Establish a standard which overprotects.

For all of these reasons, the $10^{-6}/70$ annual risk ceiling seems reasonable. The standard would allow an individual to accumulate a 1/1,000,000 risk over 70 years, however, it governs the RATE OF ACCUMULATION, ensuring that risk is not built up more rapidly during critical childhood years.

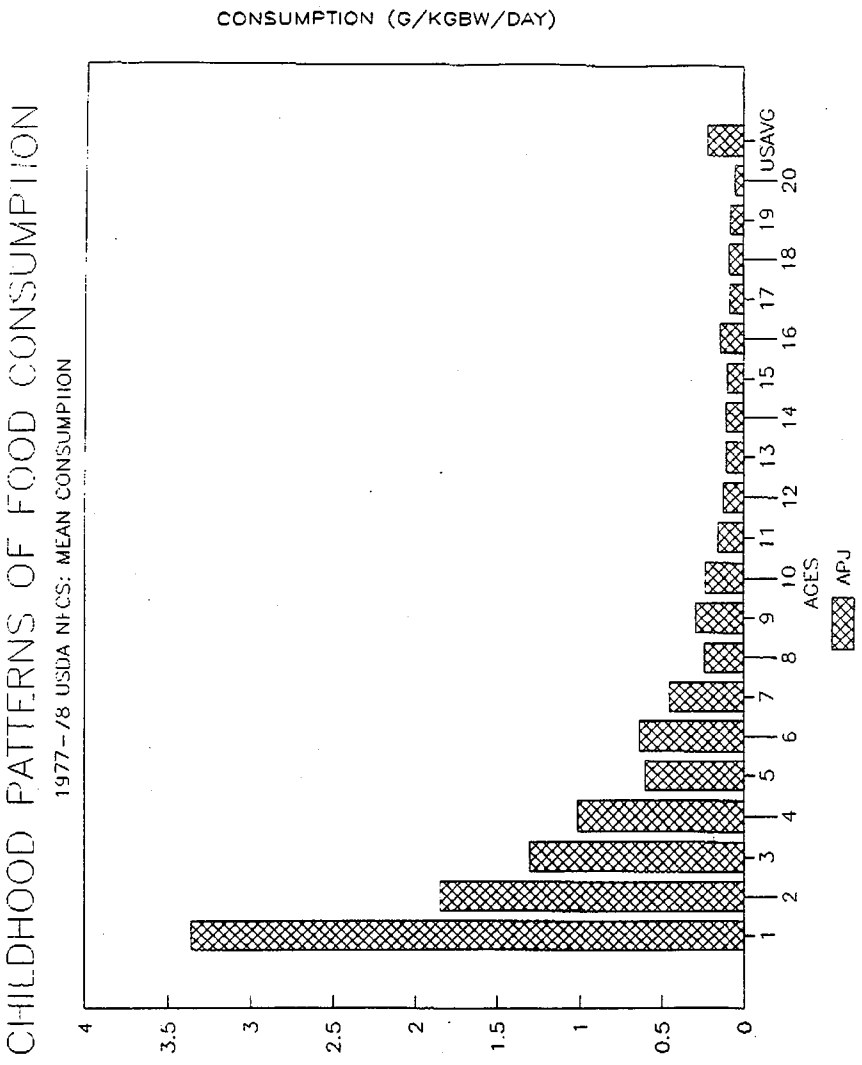
I have a colleague here at Yale, Charles Lindblom, who is famous in part due to his articulation of a theory of decisionmaking now known as "disjointed incrementalism". The tolerance-setting process is both disjointed and incremental. While there are some 320 pesticides allowed for use on food (along with 1200 inert ingredients), EPA considers only one chemical at a time.

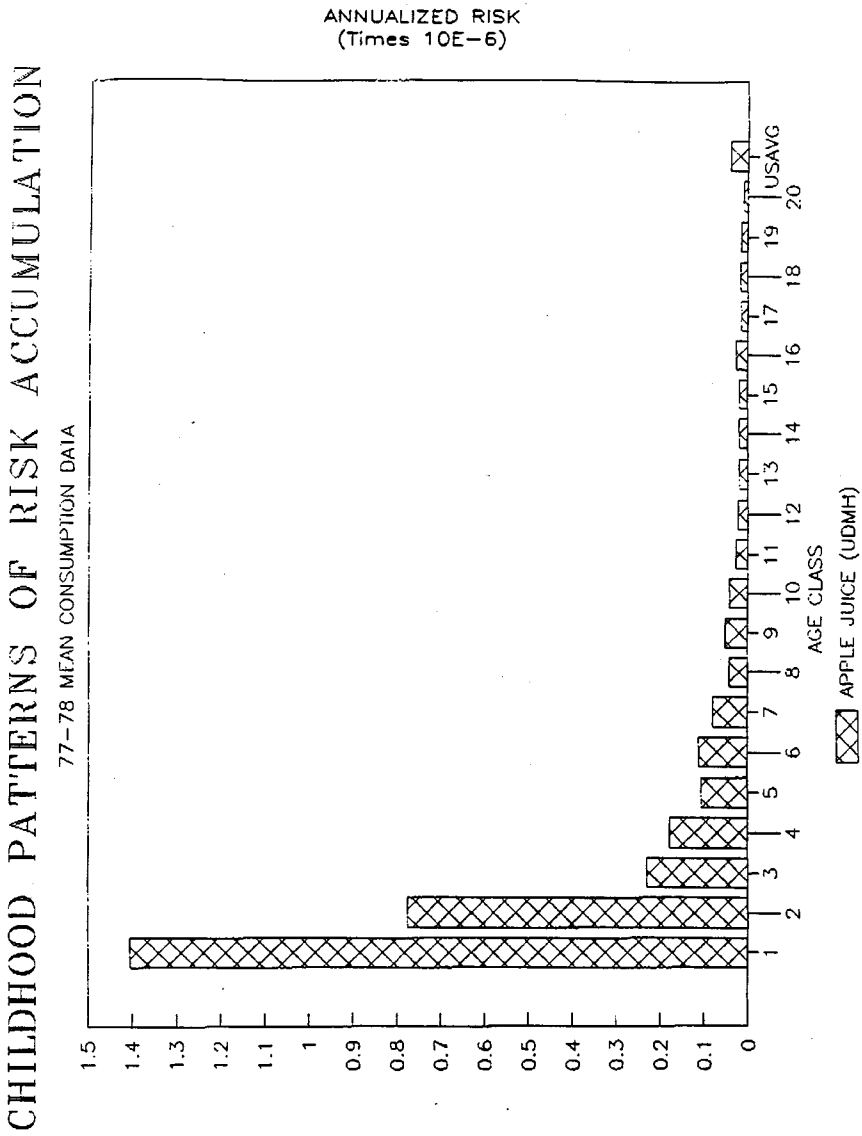
Please recall that the $10^{-6}/70$ risk standard in this bill applies only to a single chemical, despite the existence of 319 other chemicals which the Agency allows to exist as residues in our nation's food supply. In 1987 during the preparation of the Delaney Paradox report, the NAS Committee found it necessary to limit their review to only 28 chemicals which were then classified by EPA as either possible or probable cancer inducing compounds. EPA has published a more recent list of suspected carcinogenic pesticides which includes 75 compounds. Clearly, as toxicity testing protocols become more stringent, more compounds are being tested, yielding positive oncogenic results. Also, advances in residue detection technology is allowing us to find residues where, using older methods, we thought they did not exist. It is my opinion that this trend is likely to continue.

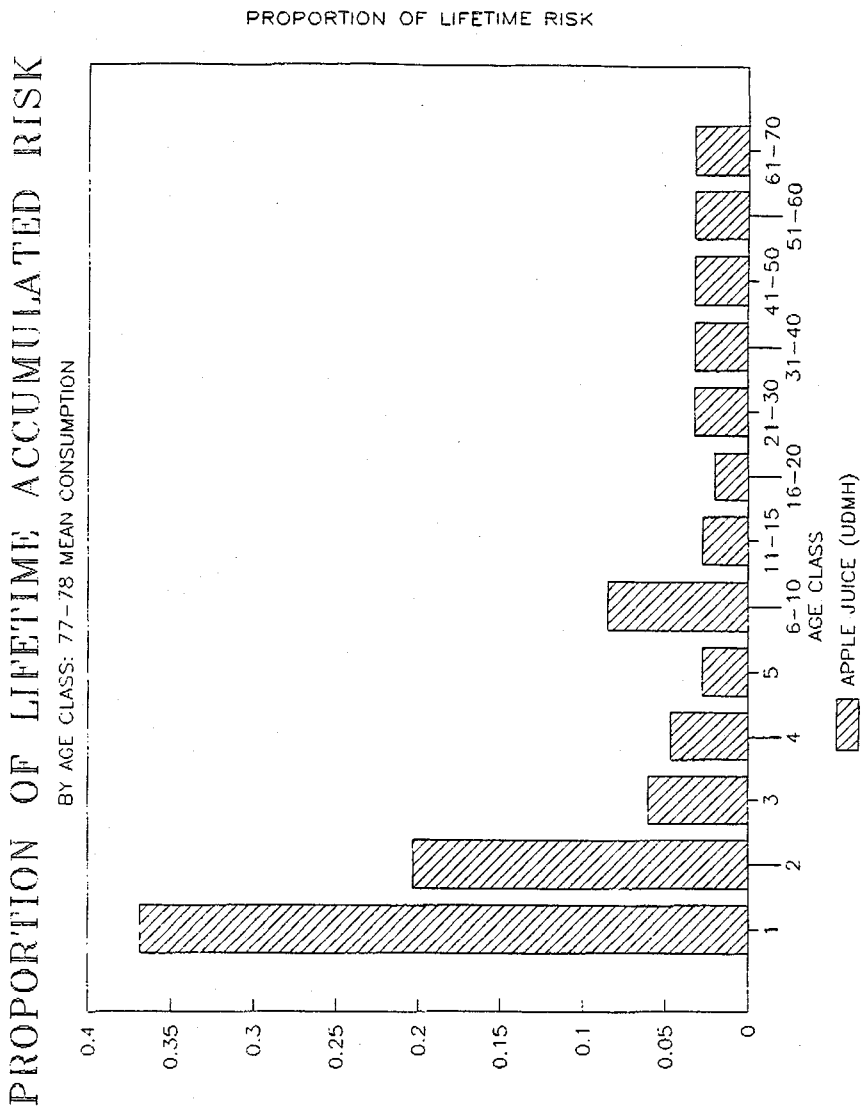
For the sake of simplicity, let us assume that within the next 5 years we all agree that 70 of the 320 compounds are found to be oncogenic, and therefore require the application of the $10^{-6}/70$ standard. This means that a simple the standard we are considering today would allow the accumulation of $10(^{-6})$ risk per year, per individual, or 70 times 10^{-6} risk over a lifetime ($7 * 10^{-5}$)). This would be an average level

VI. CONCLUSION

The negligible risk standard proposed within this bill would offer substantial additional protection to children. By contrast, choosing a simply one in one million risk standard per chemical fails to regulate the rate of accumulation of risk, essentially allowing a "front-end loading" of risk during childhood. Also, the a simple one in one million risk standard neglects the fact that there are over 300 food use chemicals permitted to exist as residues on foods, and as many as 25% of these may be oncogenic. Total dietary risk from all oncogenic compounds could easily exceed 1 in 100,000, perhaps even 1 in 10,000. This concludes my testimony and I would happy to entertain questions.


CHILDHOOD PATTERNS OF FOOD CONSUMPTION
1977-78 USDA NFCS: MEAN CONSUMPTION
CONSUMPTION (G/KGBW/DAY)
0
0.5
1
1.5
2
2.5
3
3.5
4
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
USAVG
AGES
APJ


CHILDHOOD PATTERNS OF RISK ACCUMULATION
77-78 MEAN CONSUMPTION DATA
ANNUALIZED RISK
(Times 10E-6)
1.5
1.4
1.3
1.2
1.1
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
USAVG
AGE CLASS
APPLE JUICE (UDMH)


PROPORTION OF LIFETIME ACCUMULATED RISK
BY AGE CLASS: 77-78 MEAN CONSUMPTION
PROPORTION OF LIFETIME RISK
0.4
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
1
2
3
4
5
6-10
11-15
16-20
21-30
31-40
41-50
51-60
61-70
AGE CLASS
APPLE JUICE (UDMH)

The CHAIRMAN. Thank you.

Dr. Jackson.

Dr. JACKSON. Good morning, and thank you, Senator.

I am Dr. Richard Jackson. I am a pediatrician with expertise in epidemiology, toxicology and public health. I am chairman of the American Academy of Pediatrics committee on environmental hazards. I am also president of the Association of State and Territorial Health Risk Assessors, an affiliate of the State health officials organization. I am also branch chief for the California Department of Health Services, dealing with risk assessment for air, water, pesticides, food and Proposition 65.

But today I am speaking on behalf of the American Academy of Pediatrics. I am also privileged to serve on the same National Academy of Sciences committee that Dr. John Wargo is, and nothing in my statement should be construed as reflecting the opinions of that National Academy of Sciences committee or of the Academy of Sciences. Those deliberations are obviously confidential.

The thrust of my testimony today is that while the food supply appears to be generally safe, the legal allowable limits for pesticide residues in food, the tolerances, do not always reflect safe levels for everyone, especially children.

Because of the large amount of food and drink, the increased caloric intake, the increased fluid intake, the increased oxygen use by children that Dr. Wargo has talked about, and because kids are more sensitive to certain toxicants than are adults, if we protect kids we are going to protect all consumers.

There was an interesting episode last year in Michigan where a chemical, mercury, has been used for years in paint. It was used to keep fungus down in paint. A child was discovered to have a disease called acrodynia, which is where the face, the tongue, the hands and the feet turn red, and the skin starts peeling, and it turned out to be due to the mercury in this paint.

The point of this is that it wasn't an adult, it wasn't the painters that showed up as the most sensitive organism or the sentinel event. It was a child. And if we are protecting kids, we are going to protect everyone, and that's one of the points I want to make here.

I have some secondary points that I want to discuss for just a minute, and then I'll come back to the main point about tolerances.

One point is that acute toxicants, things that make someone sick right away—the aldicarbs, the Guthions, the Phosdrins, the chemicals that were found in the potatoes and the bananas—need to be scrutinized much more than they have been up until now.

Senator Simon talked about going into the migrant camps, and clearly—I have investigated a lot of farm worker poisonings—it is the acute chemicals, the people who go into the field and begin vomiting right away. These are the same chemicals that I don't think are really being looked at adequately in terms of food residues, and I think we could take care of both workers and the public at the same time by scrutinizing these chemicals more.

I think also that the folks who are regulating these acute chemicals tend to look at them one at a time, and yet some of you will go home, and your home has been treated for termites with a chemical called chlorpyrifos, or Dursban, which slowly breaks down and can get into the home environment. If you go into the local cafete-

ria—and I'm sure the chef's kitchen downstairs—the floor has been sprayed with this same chemical to control roaches. If your home happens to have fleas, and someone sets off a flea bomb in that home, and it filters down onto the rug, and you have a baby that is crawling around or rolling around on the floor, it is that same chemical chlorpyrifos.

If you have your lawn treated with various pesticides, chemicals of the same chemical category are used in that lawn treatment. And by looking at each chemical individually and not looking at the overall impact of these chemicals, we are not serving children very well. So I'd like to see much more scrutiny of these chemicals as a group, particularly because a lot of them operate through the same chemical pathways or same human health pathways.

Now I am going to come back to my main point, because this is a point that is required already in law. The Federal Food, Drug and Cosmetic Act requires that the tolerances, the legal limits for pesticides in food, be health-protective. And I think they should be health-protective. They ought to be health-protective for adults, for children, for vegetarians, for ethnic minorities. I mean, what's the purpose of having a legal limit if it is not protective?

In fact, we recommend as public health authorities that people at lots of fruits and vegetables and grains. If they do that, if their doctor tells them to eat lots of bananas because you are on diuretics for your heart disease, it ought to be safe for the elderly person who is being told to eat bananas, or the baby who is being told to eat your broccoli.

I indicated that the Federal Food, Drug and Cosmetic Act requirement that these allowable limits be safe is being disregarded. Let me give you an example.

There was a flap recently about aldicarb. This is a chemical that inhibits an enzyme in the body and causes salivation and diarrhea and other acute illness symptoms. Aldicarb is allowed on bananas at .3, three-tenths of a part per million. If a 17-pound baby eats one banana at the legal allowable limit, they are getting 30 times the acceptable daily intake of this chemical. They are getting about 6 micrograms per kilogram, and that is about the level that we began to see symptoms in the great watermelon outbreak in California. It is about one-tenth the level that we saw someone almost die in the aldicarb episode in California.

So there is clearly not an adequate margin of safety for some of these chemicals, especially for kids.

Now, you are going to hear a lot of arguments about why these legal limits should not be safe. One argument is that, well, there is lots of testing. We have these fancy datasets that tell us that the actual residues in food are much lower than the legal limits. As someone pointed out, it is sort of like saying that the speed limit is 350 miles an hour, but everything is fine because most people only drive 100 miles an hour.

I would argue that if you really sit down and scrutinize the systems where they actually sample food and look at the pesticides in food, that no one really knows what the actual residues in food are. A chemical like aldicarb, the most seriously toxic chemical that is sold, was used for a dozen years before it was discovered that hot potatoes, toxic potatoes, could get into a child's diet. It was used for

a dozen years before it was discovered that toxic bananas could get into a child's diet.

So telling me that everything is safe because it meets tolerances is very cold reassurance.

The other argument you are going to hear is that, look, these chemicals have been used for years, and where are the bodies. We don't see anyone really being proven as sick from pesticides. I heard this over the aldicarb and bananas argument.

We investigated a case in 1988 where two people ate taquitos, a snack food, in Orange County, and within a few minutes the stepfather and son developed generalized seizures, grand mal convulsions, and had to be taken away by ambulance to a hospital. They were put on anticonvulsant drugs. The uncle lost his driver's license. It was discovered to be due to a chemical, the illegal use of endrin, someone had contaminated the food with endrin, an insecticide.

When we heard about that, we did a followback, public notification in that county, several months later, and we discovered three more people who had had to be carried by ambulance to a hospital, had to be treated for generalized seizures, who had lost or were in the process of losing their driver's licenses, and they had never been discovered.

Now, imagine with an illness episode of that severity, when they go undetected, not picked up, what happens when a pediatrician sees a baby with a little too much diarrhea or a little tearing or a little too much urination. Who would think of sending off a banana for a $500 pesticide analysis? It really just doesn't happen. So you don't have a reasonable system to track down acute illness episodes, and anyone who tells you that the fact that we don't have bodies means everything is fine, I think they are basically dissembling to you.

In the case of aldicarb in bananas and in potatoes, where we found these individual food samples—and some of them high enough to be within one-tenth of the level that would be lethal—my assessment is over the last dozen years or so that Americans have been becoming ill from residues in food, and it was just too difficult to pick these up, but in fact, illness has been occurring.

I have some other arguments that I can go through about why things ought to be fixed; they are in my written testimony, and you can look at it yourselves.

I think the point of aldicarb in bananas shows that out-of-date and nonprotective tolerances hurt everyone. They hurt the public, of course. They also hurt chemical companies that are seeking to get licensed new and safer products, and they also hurt farmers who are growing food in the belief that they are doing the best they can and adhering to the law and then finding out that the food they are producing has no safety margin, and they run the risk of the loss of public acceptance.

In situations where it can be shown—I have heard arguments—in fact, I read the former surgeon general's testimony that there have been great health benefits from having cheap food because of pesticides. I am not sure how much cheaper food is actually because of pesticides. And clearly, if there are health-health tradeoffs that need to be made—and by that I mean if you can show

that there are health benefits from the use of various chemicals, then I think we ought to make these trade-offs.

In the area of chlorination of drinking water, we chlorinate water in order to prevent typhoid, and we know that that leaves a long-term cancer risk, a low but long-term cancer risk. And that trade-off is made explicitly in the public record. Everyone is aware that this trade-off is made. And I'd like to see the same set of trade-offs made publicly for pesticides in food.

I think in summary the point I'd like to make and leave you with is that the regulatory limit on food, the pesticide food tolerance, should be the tool for health protection.

I thank you very much for your interest in the protection of children and for allowing me to testify.

[The prepared statement of Dr. Jackson follows:]

Prepared Statement of Dr. Jackson

Good Morning, I am Dr. Richard J. Jackson. I am a pediatrician with expertise in epidemiology, toxicology and public health. I am Chairman of the American Academy of Pediatrics (AAP) Committee on Environmental Hazards, president of the Association of State and Territorial Health Risk Assessors (ASTHRA), and head of the Risk Assessment Branch for the California Department of Health Services. Today I am Speaking on behalf of American Academy of Pediatrics (AAP). I am also privileged to serve on the National Academy of Sciences (NAS) Committee that is working on issues related to this hearing, but those deliberations are confidential, and my testimony should not be construed as reflecting the opinions of the committee or of the NAS.

The American Academy of Pediatrics is an organization of 40,000 pediatricians dedicated to the well-being of children. The Academy has had a long standing and core membership interest in the issue of children's diets, and concern about toxicologic hazards to children.

The main points of my testimony today are that while the food supply appears to be generally safe, the legal allowable limits for pesticide residues in food, the pesticide, do not always reflect safe levels for everyone, especially children. Because of the large amount of food and drink that children consume relative to body weight, because they consume a limited variety of foods, and because of their increased sensitivity at certain developmental stages, if pesticide tolerances are safe for children, tolerances will then be safe for all consumers.

Children drink more fluids, consume more calories, eat more of certain foods, especially milk, soy, and fruit, than do adults. They are more sensitive to certain pesticides than are adults. For example, last year a child was found with the acrodynia, a serious illness related to mercury toxicity, that resulted from the fungicidal compound, phenyl mercuric acetate, (PMA) in indoor latex paints. The greater sensitivity of the developing human

brain to lead or mercury, or the developing bone marrow to radiation are further examples of the sensitivity of the growing child.

Some secondary and specific points which I will mention but will not discuss further in my testimony are:

that acute toxicants used on foods require more scrutiny. The experiences with aldicarb in potatoes and bananas are forewarnings that we should pay attention to acutely toxic pesticides, at least as much as we are concerned about long term effects.

that those agencies deciding allowable levels in food should assure that some margin of safety be provided for non-food exposures to these same chemicals. For example, chlorpyrifos is used extensively on food, but it is also used throughout a child's environment: as a termiticide, as a flea bomb, as a roach spray, and as a lawn pest treatment. When we decide acceptable levels for chemicals in drinking water, we always assume exposure by other routes, especially food. In contrast, acceptable food levels are decided without consideration of other routes of exposure. and

that chemicals having the same toxicologic effects, such as the organophosphate and carbamate pesticides, should be regulated as a group, and not only as individual and unrelated compounds. For example, chlorpyrifos, the pesticide I mentioned above, shares its toxic pathway, cholinesterase inhibition, with many other pesticides used on food and in the home.

I now return to my main point. It would seem self-evident, in fact, it is already required under Food and Drug law, but not adhered to. Legal allowable limits for pesticide residues in food, the pesticide tolerances, should be safe, that is, they should afford an adequate margin of safety for any consumer, adult, child, vegetarian or ethnic minority.

Diets rich in fruits, grains, and vegetables are the very diets that we health authorities recommend to the public. Clearly, the highest amount of pesticide residue legally permitted in food should be a level that would allow a child to consume apples or peaches *ad libitum*, or an elderly person on medication to consume bananas or bran as needed, or a vegetarian to consume legumes and grains, as required.

I indicated that the Federal Food Drug and Cosmetic Act requiring that allowable limits be safe is being disregarded. For example, with the example of aldicarb sulfoxide in bananas, a 17 pound child (7.6 kg) eating one banana at the legal allowable limit of 0.3 ppm would be getting a dose of 6 mcg per kg, 30 times the Acceptable Daily Intake or reference dose for aldicarb sulfoxide. As we learned from the aldicarb in watermelons outbreak in California, this was the range where symptoms such as nausea and diarrhea

appeared. In that outbreak the most severely ill person was one woman who nearly died from eating 56 mcg per kg of aldicarb.

Opponents to these reforms offer the following excuses for why the legal limits do not have to reflect safety; let us examine these arguments:

Argument 1. Extensive residue food sampling shows that actual residues are far lower than the legal tolerances, therefore the tolerances need not reflect safe limits.

Response 1. The problems with this argument are that no-one truly knows what the actual residues are. Aldicarb was used for years on potatoes and bananas before any sampling of individual food items was performed and it was discovered that residues could be very high in individual bananas or potatoes as people actually ate them, rather than as the average of a boxcar load, the more likely sampling routine.

Residue testing is generally used as a regulatory compliance tool and is not intended to adequately profile actual residues. It is generally not timely or extensive enough to be a true consumer protection tool. It works to signal pesticide users that if they misuse, they might get caught, and to protect those who use the pesticide properly.

There is extensive testing of food by FDA, USDA, the States, especially California, and by private Industry.

The problems with much of this sampling are that:

Acutely toxic chemicals are sampled for in food batches, rather than in individual food items, as the consumer would likely eat them,

the level of sensitivity used to test for the chemicals is often set at, or within an order of magnitude of, the too-lenient tolerance,

the lab methods are used to scan for some but not all chemicals used on that crop, or they scan for chemicals not used with the consequent false assurance about the pesticides not found,

the results are not collected with background data or reported to any central repository,

the methods used vary by laboratory and we do not really know what the so-called negative results actually mean.

The reality is that no one truly knows what actual residues in food are in domestically produced food and even less is known about imports.

Argument 2

There is virtually no evidence of human illness from legal residues of pesticides in foods, therefore there is no need for concern.

Response 2

Dramatic episodes, such as 1000 people made ill, and two fetal deaths, from illegal contamination of watermelons with aldicarb in 1985 in California are fortunately very rare. On the other hand, if this contamination had been

with a chronic toxicant potent carcinogen or reproductive toxicant, the human disease following months or years later would have gone unidentified.

Even in the case of severe acute poisonings, cause and effect is very difficult to identify. As an example, in 1988 in Orange County there was an episode of contamination of a snack food called taquitos with the powerful insecticide, endrin. Two members of a one family, a stepfather and son, who had eaten these snacks developed generalized convulsions, *grand mal* seizures, and required emergency treatment. The stepfather faced loss of his driver's license because of a diagnosed seizure disorder. Believing this to be a local contamination incident, FDA did not notify other local purchasers of the product. When the California Department of Health Services learned of the episodes and followed up, it was discovered that 3 other people had also become ill, were facing loss of drivers' licenses and were receiving anticonvulsant therapy. If pesticide food poisoning cases as severe as ambulance-requiring generalized seizures go unrecognized as pesticide poisoning, as it did in the later cases, how do we expect more subtle symptoms to be identified? How do we expect an elderly woman on heart medications to identify her diarrhea, muscle twitching, or mood changes as related to dietary pesticides. How is any pediatrician going to make this diagnosis in a toddler?

In the cases of aldicarb in bananas and in potatoes, individually sampled foods were found well over the inadequate and nonprotective tolerance, a young child consuming the most seriously contaminated foods could receive a dose within an order of magnitude (ten times) of the LD_{50}. My assessment of these findings is that, in fact, over the years Americans have been becoming ill from these residues in potatoes and bananas, but that it was too difficult to discriminate these symptoms from other causes of headache, nausea, diarrhea, muscle and mood symptoms.

There is a lack of real post-market illness surveillance. It is very poor for pesticide worker illnesses, and virtually nonexistent except for the most obvious and dramatic food related illnesses.

Argument 3

Only a limited portion of a crop will be treated with a specific pesticide and therefore assuming all foods have the legal allowable limit will grossly overestimate the population's exposure.

Response 3

This point is well taken, except for a child living in Florida it is likely that all her green beans will be treated with fungicide: fungicide use patterns in California or New York are irrelevant to her.

Because pesticide use patterns change so dramatically year-to-year and place-to-place, the only way to account for the issue of "proportion of crop treated" is to cap or limit use in the pesticide permitting process, and this is infeasible.

Argument 4

The tolerances for food are actually enforcement tools to ensure compliance with the legally required conditions for use of the chemical in agriculture. They are not intended as health standards.

Response 4

Today will you hear that "the food supply is 'safe' because 99% of domestic and 97% of imported food is below tolerance". This argument only works if the tolerances are set, as required in law, at safe levels.

The reality is that as long as the tolerance is the only regulatory standard, the only legally enforceable limit, the FD&C Act and the California Health and Safety Code are correct in requiring these standards represent safety. As the example of aldicarb in bananas shows, out-of-date and non-protective tolerances hurt everyone: the public of course, but also companies seeking to register better replacement chemicals, and farmers who grow food with pesticides that may leave residues with no safety margin and who run the risk of loss of public acceptance.

This committee will hear arguments that the proposed reforms are too extreme, that they will affect a cheap and abundant supply of food, and that they will affect minor crop uses.

We have heard these arguments for a long time. The loss of the carcinogenic food contaminant EDB did not lead to grain shortages or weevil-filled flour, it led to clean-up of milling operations so that vermin control was done with hygiene rather than with a worker and consumer-endangering gas. The cancellation ten years ago of the spermtoxic and carcinogenic ground water contaminant DBCP did not result in the end of California grape or tree fruit production -- there are still plenty of grapes and oranges; and apples are still delicious and plentiful and profitable without Alar.

In those situations where it can be shown that a more stringent pesticide tolerance would endanger rather that improve public health, this rationale should be presented explicitly and publicly. In the case of drinking water chlorination, society rightly trades off the risks of chloroform residues to obtain the benefits of waterborne-disease prevention; the same should be done with pesticides in food, but openly, not covertly, and with the health benefits accruing to those who bear the health risks.

On the issue of "minor uses" I suggest that suitable compromise language can be worked out. There should be some way both to protect our kids and to save our Kiwi fruit.

In summary, the only regulatory limit on food, the pesticide food tolerance, should the tool of health protection. Protection of crops is important, but not more important that the protection of our children.

I am grateful for the opportunity to speak to the committee today. I and the members of the Academy of Pediatrics, commend and support your interest in the well-being of children.

The CHAIRMAN. We'll follow a 10-minute rule.

Let me ask you this—even if we establish these standards that both of you refer to, how are we going to be able to really ensure the safety of children in the general population, when we don't know how much is being used on various products?

We can develop a standard here that only if "x" amount of any of these pesticides is used will the product fall into a standard that we decide is safe. Yet, some may still use more, some may use less. Doesn't this sort of get into "never-never-land"? How are we going to deal with those kinds of issues and questions?

Mr. Wargo.

Mr. WARGO. I think my response would be that the standard should be based upon health criteria. In other words, you would set the tolerance to be health-protective. And therefore all of the guidelines of how the chemicals should be used in the field for all the different crops would be clearly specified by EPA to minimize the possibility of having residues above that health-protective level.

I think Dr. Jackson's point that the tolerances should be health-based is a crucial point, and I think that would solve the problem.

The CHAIRMAN. Dr. Jackson, would you agree?

Dr. JACKSON. Absolutely. I mean, why deal with the complicated issues of what percentage of the crop is treated, or devising an incredibly complicated system to do extensive sampling when in fact just set the legal standards at the health level, and you cut the Gordian knot.

The CHAIRMAN. That's making the assumption that those standards are being followed, but that is obviously something that has to be pursued by a regulatory process.

What is your response to those in EPA who say we're already providing these kinds of evaluations of children's needs? These people believe that, basically, all we need to make it work is the mandate of Congress, and that as such, we must fashion and shape a process or a system that will be able to take this into account. Above all, they believe that what we don't need is a lot of micromanagement in terms of establishing these tolerances for the various chemicals. How do you respond to them?

Dr. JACKSON. I number one want to commend the EPA leadership. They recently have done a very good job in this area, and I want to verbalize that, number one. No. 2, since they are already doing it, what is the problem with this bill? I mean, if this is simply codifying what is existing practice, then just let it be. And number three, if they need to relax or seek a different risk assessment number in various situations, give them an explicit trap door to allow them to do that. But if this is existing practice, then let it be.

Mr. WARGO. Senator, if I could respond to that.

The CHAIRMAN. Yes.

Mr. WARGO. It is not possible for EPA to be capable right now of accurately assessing childhood exposure because of the lack of availability of good residue data as well as recent consumption data, and also the way they have structured their data allows them only to assess exposures and risks in gross age classes—say, kids between the ages of one to 5, or 2 to 6.

If you look at this chart over here on the left, you see some rather dramatic changes occurring between that period that could have toxicological significance to a young child. So the limitations in the data that they have available to them as well as the way they use that data all would cause them not to be able to assess these risks, and I don't believe that their current methods are appropriately protective.

The CHAIRMAN. I think, Professor Wargo, you mentioned the data available is 13 years old; is that correct?

Mr. WARGO. Yes, that's correct.

The CHAIRMAN. Do you have recommendations as to how that can be upgraded? I suppose it is by simply requiring the producers to make that information available, much as we try to do in the legislation. But how do we address that particular challenge? The FDA is inundated at the present time. We've got a good director there now, attempting to do the job, but how are we going to get that kind of information? Whose responsibility is it?

Mr. WARGO. Well, if you require that residue data be collected that is statistically reliable for the purposes of exposure assessment, and you require that consumption data be collected that is statistically reliable that allows you to go back and project these risks onto subpopulations of children or, as Dick Jackson was suggesting, children who are vegetarians who live in California, this data needs to be recent, it needs to be designed statistically specifically for the purpose of exposure and risk assessment. It is not a difficult thing to do. It takes money, and it takes time.

If I were going to characterize the current regulatory system, I would say that it was either designed by Rube Goldberg or Oliver North in terms of legislative responsibility allocated to the different agencies.

EPA sets standards. USDA is responsible for assessing benefits. FDA is responsible for monitoring and enforcement. My gosh, you are setting up a system here that is so complex, that requires these people to talk to one another. They all use different computer coding systems that make it very, very difficult to come to a conclusion about what the level of exposure is out there. This responsibility, in my mind, should be centralized.

The CHAIRMAN. How do you respond, both of you, to the suggestion that if we follow this kind of criteria which you have indicated to be necessary in terms of the protection of children, aren't we really looking for confusing arithmetic? What's wrong with spreading this risk over 70 years? So admittedly, there is greater risk in the early years and less going on, but we're talking about imprecision and about these particular pesticides. If we decide that it is over a lifetime of 70 years, it is somewhat front-loaded to an extent, but it is over a longer period of time. Plus we show that though there is a special sensitivity in children due to their body weight, rapid organ development, and eating patterns, it is still a one in one million standard: it is a pretty safe standard. Why don't we just look at it over that period of time? What's wrong with that? Otherwise we're going through this complicated arithmetic and bureaucratic regulatory process, which is going to mean a considerably more costly food supply for the American consumer, and that the American consumer may very well eat other kinds of

products which won't be as healthy for them. Therefore, in terms of the total issue, we are really acting counterproductively.

Mr. WARGO. One response is that most tumors seem to take a latency period of 20-40 years to develop. And most theories of how tumors do develop are thought of as being multistaged in their character. In other words, a cell would have to be hit by an oncogenic agent on more than one occasion, and there are various theories about how many times that must occur. But I think quite clearly you could understand that if a child were initiated, so to speak, if a child's cells were hit by a toxic agent early on, they have a much longer period of life when later stages might occur.

So it is a statistical issue of increasing the probability of tumor development over longer periods of time.

The CHAIRMAN. Dr. Jackson.

Dr. JACKSON. The practical reality is that radiation exposure, known carcinogen, if it occurs early in life greatly increases a child's risk of cancer. Diethylstilbestrol exposure, if it occurs during a little girl's development in utero, greatly increases her risk of ultimately developing genitourinary cancer.

Early cancer is a tragedy for the family where it occurs, and clearly we ought to be focusing on protecting at the early phases.

The CHAIRMAN. I am well aware of that.

Let me just ask you—and then my time is up—whether you feel that the sense of urgency about this particular issue is sufficient that we would be acting responsibly—in establishing the kinds of standards which you both have commented on, before the Academy of Science makes its recommendation? I imagine that this is really a political judgement, but it is a judgement that must be made by people who know this question and issue well.

Dr. JACKSON. My suggestion, Senator, if I may is that I believe the system is broken. I believe it needs to be fixed. If the Academy of Sciences report comes out that would change anything, perhaps the committee would want to think about a way to leave some latitude to adjust certain of the risk assessments to accommodate what came out in that report.

But I don't see anything in this piece of legislation that doesn't appear to me to be obvious common sense. I would just recommend that you go with it now, and then if adjustments need to be made later, go ahead.

The CHAIRMAN. Professor Wargo?

Mr. WARGO. I would agree with that. Another way of interpreting Chart 2 here is to think about the implications of regulatory delay. A one-year delay for a single chemical could cause a substantial increment in risk, one that I think people are not comfortable with. So I guess my argument would be that I would like to see the standard in place as quickly as possible; that the improvement in making the tolerances health-based occur as quickly as possible.

These 10-, 15-, 20-year delays in the regulatory process allow in my mind unacceptable levels of risk to be accumulated, particularly in children.

The CHAIRMAN. Senator Kassebaum.

Senator KASSEBAUM. Thank you, Mr. Chairman.

I am sure those of us who followed this through last year's debate, many had hoped that there could have been compromises

worked out last year to resolve the issue, and it seems like deja vu all over again.

On the other hand, I think we all agree that the legislation that we're talking about, the Federal Food, Drug and Cosmetic legislation, has not been significantly changed in the last 20 years, and it is important to address the issue in a way that the public has some confidence that indeed we are trying to, as you say, make sure that the current methods are protective—I think, Dr. Jackson, that was the word that you used—and that the current methods that we are using, you both question.

I would simply say—and I'd like to make my full statement a part of the record, Mr. Chairman——

The CHAIRMAN. It will be included in the record.

Senator KASSEBAUM. [continuing]. That before everybody stops eating bananas, that I don't believe you added that aldicarb has been temporarily stopped and voluntarily withdrawn from the market. That didn't occur until the first part of June, and I'm sure that the questions that were raised prompted this action, but I think that the manufacturers are to be complicated for taking that action and recognizing that further research needed to be done.

Dr. JACKSON. I would like to clarify that point that as soon as the information was brought by the manufacturer to EPA that clearly the manufacturer and the banana producers acted in an extremely responsible way, did not allow entry of bananas from aldicarb-treated fields into the United States—even the suggestion that someone could become ill caused them to change their marketing patterns—and I absolutely agree that they should be commended, and I'd like to make that clear.

Senator KASSEBAUM. Because I think it is important. Something like this goes out, and everybody then gets alarmed, and that's my concern with this issue, that out of our desire to try to find something that works and put a legislative vehicle together that allows for some flexibility, we don't also raise such alarm bells which cause people to stop eating bananas or stop eating apples, and we try to address it in a responsible way, that we don't use the worst-case scenario necessarily because I think the public as a whole has become absolutely—it's a little like the little boy crying "Wolf". They don't understand, and each week there seems to be something new that may be hazardous to one's health.

And I think if we want to convince the public that we're all responsible in this issue, we have to do it in such a way that, as I say, we don't take a worst-case scenario and let it become the headline. And as we sort through the solution in these hearings, I hope that this will be valuable.

I was interested in your suggestion, Dr. Jackson, that the tradeoffs be made public, that without just sort of alarmist bells going off all the time that there is again a greater sense of perhaps accountability in what is made public so that the public can assess and understand exactly what is happening, and for the public's protection of health, there may be tradeoffs that have to be made.

But given that, at least we have addressed it in an honest fashion. I come from an agricultural State, Kansas, and this has frequently been an issue that has pitted the environmentalists, so to

speak, against the agriculture interest or agriculture-related interests. We all have agricultural interests in our States.

But I think those who are engaged in agriculture want to be responsible as well, and finding the best legislative compromises to do so, so that we can make sure the health problems are addressed.

When you were talking about the bananas, I couldn't help thinking of my 15-month-old grandson, who eats a lot of bananas. Well, again, I think it is terribly important that we make sure that the public is not going to become so frightened of this that we all wonder whether we should or should not eat bananas.

Dr. JACKSON. Senator, I have sort of a cognitive dissonance about this because I end up wearing two hats. As a physician who is called by fellow physicians saying their patients are coming in, and people are in a panic about something, my response is, no, you don't need to run out and dump the apple juice down the drain. You don't need to worry about individual bananas. But from the public health side, the people who are organizing or in charge of this system, who are deciding what is allowed, who are making decisions for 200-300 million people at a time, have very serious responsibilities, and when those fail to be met—and frankly, I think they were not met in the whole issue around alar—it ends up on the individual mother's breakfast table when she is trying to make sense out of something that should have been dealt with in a regulatory process years before.

So I couldn't agree with you more. This is not something that we in any way want to put before the public and alarm them with. It ought to be fixed before that.

Mr. WARGO. Senator, if I could comment briefly, I think you are raising a very important issue with respect to benefits, and the standard that is being proposed is an alternative to risk-benefit balancing. It is simply a health-based standard rather than a risk-benefit balancing standard.

Let me make two points about benefits. There are no clear guidelines on how benefits associated with the use of a chemical should be expressed. Traditionally, if you look in the Federal Register at the technical documents, they are expressed in terms of crop production, potential job losses, farm income loss—all very important. But there are other cost considerations that I think of when I think of the concept of benefit. I don't think really of this process of risk-benefit balancing as being that simple. I think of it as being risk-benefit cost-balancing, because there are health care costs that are associated with treatment of tumors—I had a student who went to our medical school and found that the average cost of treating a tumor at Yale University is $50-$100,000. If you take some of the projections of number of tumors that are expected over a fair number of years, you come to very large dollar figures, yet those estimates are not included in the benefits equation.

So my argument really is that an expanded conception of benefits and costs has to be considered.

Now, the other worry is if you implemented this standard, what would the economic effects be. Would there be certain specific crops that would take a much harder hit than others. I think the answer is yes. But there are ways of mitigating that, including phasing in the standard over time to allow for the introduction of

less risky chemicals and also to allow farmers to learn techniques that do not require as extensive use of chemicals.

There is a very important and very interesting publication by the National Academy Press that came out last year on alternative agriculture, demonstrating the potential for maintaining crop yields across a diverse set of crops without the use of agricultural chemicals or with dramatically lower levels of chemical use. So that this phasing in process of the regulation I think could mitigate the distribution of costs that might be associated with the standard.

Senator KASSEBAUM. I think you both have had very valuable testimony, and I certainly appreciate it.

Thank you.

[The prepared statement of Senator Kassebaum follows:]

PREPARED STATEMENT OF SENATOR KASSEBAUM

Mr. Chairman, I appreciate having the opportunity to express my concerns regarding S. 1074.

Given that the Federal Food, Drug, and Cosmetic Act has not been significantly am,ended in 20 years, it is no surprise that problems in the current regulations have surfaced. But I do urge caution in that the new legislation should allow ample flexibility in determining risk/benefit calculations and should be based on sound, reasonable science.

The current debate has often pitted those typically known as the environmentalists against many in agriculture and agriculture-related industries. Overwhelmed by mostly good intentions and a barrage of misconstrued statistics and reports, we are being confronted with a number of misconceptions.

Dduring the past few years, those depicted as environmentalists and those depicted as representatives of agriculture, including farmers, have been "preaching to their own choir" in an attempt to address this dilemma. Unfortunately, we have only succeeded in blaming each other. I do, however, believe that it is clear that changes in current law need to be made. I am hopeful that throughout this dialogue common sense will prevail, thus allowing us to address pesticide problems and many related misconceptions.

Now, I would like to comment briefly on S. 1074. This bill concerns me for several reasons. First, in order to address the concerns of many consumers, I believe that risk standards must be developed which not only ensure that we have a safe food supply but allow for flexibility to cope with new scientific developments. I urge other members of this committee to recall that just 15 years ago scientists could detect up to 35 parts per billion. Today, they can identify one part per quintillion. due to these new scientific developments, provisions, such as the Delany Clause, which mandates zero risk for carcinogens in processed food, must be revised. I am pleased that S. 1074 addresses the Delany Clause, but I am concerned that other risk standards are too strict. One must keep in mind that dietary factors, excluding pesticide residues, tobacco use, and other infections are, by far, the biggest contributors to cancer in our society today. Consequently, I believe that we must keep this issue in perspective by allowing the environmental Protection

Agency to adopt reasonable risk assessment models with allowed flexibility to accommodate evolving science.

Regarding risk/benefit analysis, I firmly believe it is vital that we include both health and economic benefits in determining allowable tolerance levels. Unfortunately, this legislation contains neither. Although I agree that we must try to lessen the use of agricultural chemicals, I believe that we must also face the reality that pesticides can provide vital health and economic benefits to all consumers.

I am disappointed that S. 1074 fails to address national uniformity of tolerances. As we are all aware, this issue has created much controversy. Although there may be circumstances whereby States may desire stricter tolerances, I believe that, in general, uniform tolerances are needed. If a substantial number of States were to start establishing a myriad of tolerances, I am concerned that the impact on trade and agriculture could be substantial. The issue of national uniformity has been debated for some time, and I am hopeful that a reasonable compromise can be reached. But I do believe that any pesticide legislation will have to face this problem.

Mr. Chairman, this is an important and complex issue which is being addressed by several pieces of legislation in various committees. Because this issue affects everyone from the farmer to the consumer, I believe we should be careful and deliberate in our actions. I am hopeful that the final outcome will produce some harmony between FFDCA and FIFRA. Both of these acts concern pesticides and their use, and it is of paramount importance ton ensure that both acts work together.

The CHAIRMAN. On that last point, with the children's standard, we're not talking about many items, are we? We're talking about 15 or 18 or so?

Mr. WARGO. We don't really know yet, Senator. My guess is that if you chose the 10 most consumed foods by children, and you looked carefully at the chemicals that were allowed for use on those 10 foods, you would find that there were maybe half a dozen chemicals to a dozen chemicals that would be influenced by this standard.

The CHAIRMAN. But I think it is important that while we're talking about the children's standard we establish that we're talking about a rather limited, although very important area in regard to the kinds of items being consumed by children, are we not?

Mr. WARGO. Yes, that's very accurate.

The CHAIRMAN. We don't want it to be thought that this is just going to be a broad-based agricultural kind of an issue. I think that is important.

Senator Dodd.

Senator DODD. Mr. Chairman, I would just thank you for holding the hearing and note that one of your witnesses here is a professor at Yale and not at Harvard, which is encouraging.

I read your testimony, and one can get lost—I was particularly interested in "disjointed incrementalism" which you made reference to here.

I have a particular interest, of course, in children, and we held hearings here a year or so ago on alar—in fact in this very room—and I was stunned to discover that EPA was only considering one

chemical at a time. There is always a danger with those of us who really are laymen in this kind of a debate. But, it did seem to me on its face to not make a great deal of sense if what you were trying to determine were the cumulative effects—particularly on infants.

I guess the only question I'd raise—although Senator Kennedy's last question mitigates it to some extent—is to what extent we're in sort of a bureaucratic gridlock here. According to your testimony, we're looking at some 320 pesticides allowed for use on food, along with some 1,200 inert ingredients. It seems to me there ought to be some sense of priority.

Prior to getting into all of this, is there enough knowledge to work off of that you or someone who is knowledgeable enough, could take a look at that list and say, well, at least based on what we know right now, our attention and our priorities ought to be focused on these 10, or these 5, or these 20, or whatever the number may be. Would someone be able to get some sense of priority, given the fact that there has not been enough support and funding for the personnel levels?

We have all heard from the EPA the difficulties they have just in managing and doing a good job, and I have a certain degree of sympathy for that. It seems to me, though, that facing this reality, there ought to be some way to prioritize this list a bit. We need to give those who are least able to defend themselves or who are most dependent on a relatively small amount of food sources, and at their earliest stages of their development the highest priority. Then as the danger lessens as you point out in your testimony, that list of priorities expands.

Is that possible, or am I being terribly naive by suggesting that there is a way of dealing with the problems of lack of personnel and at the same time prioritizing a list?

Mr. WARGO. I think it is an outstanding suggestion. EPA officials should not take any of my comments as criticism of them. I have numerous friends and colleagues inside EPA and also many students inside EPA, and my impression of the quality of work is outstanding.

Senator DODD. I agree with you.

Mr. WARGO. This problem is not their problem. The problem is the result of the way the law is structured and also the allocation of budgetary resources. They are not in the business of trying to push risk on kids. They are trying to do the best job they can, given extremely limited resources.

The idea about establishing priorities is an outstanding idea. They have done that within the agency. Unfortunately, the regulatory review process proceeds chemical by chemical. The last time I counted, the number of chemicals that are allowed for use on apples was 110. For oranges, it was about 105. This is the number of tolerances that exist in the Code of Federal Regulations.

If you use computer simulation to see what the effect of cancelling one chemical that you think of as a bad chemical, posing too much of a risk at one point in time, without consideration of the possible substitutes, you run the risk of actually increasing risk because a farmer is forced into using a more risky chemical. So these chemicals have to be looked at in concert across foods, and it is a

very difficult thing to do because of the way that the data has been requested chemical by chemical.

The other question you raised was is it possible to isolate particular foods and particular chemicals so that we can attack this thing quickly. My answer is yes. My guess is that if we chose 10 foods, primarily fruits and vegetables, that we would not have to deal with more than perhaps a dozen chemicals to substantially reduce the level of exposure in the food supply. I think it is an outstanding idea and one that is clearly feasible given the State of computer technology as well as the State of data that is available to the agency and now to other people.

Senator DODD. Dr. Jackson.

Dr. JACKSON. I agree. We ended up doing the same thing in California when a bill went through called the "Birth Defects Prevention Act" that said fill the data gaps on pesticides. There were meetings where it was decided that trying to fill the data gaps on 1,200 active ingredients all at once didn't make any sense. Priority needed to be set for those that had the most use and people were the most exposed to.

Senator DODD. Thank you.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Senator Cochran.

OPENING STATEMENT OF SENATOR COCHRAN

Senator COCHRAN. Mr. Chairman, let me thank you for conducting the hearing and bringing the committee to look at the issues that we're debating and discussing this morning.

I am hopeful that this exercise will produce a consensus for some changes that are needed in regulations and the laws on which those regulations are based to help ensure that we do have a scientifically based approach to improving the safety of our food supply. I think that is an important goal, and if that is the goal that we are seeking to achieve then I fully support the effort.

I want to say also that I think the bill that is the subject of this hearing takes some very positive steps in the right direction. Its provisions to eliminate the inconsistencies in the regulation of raw and processed foods, for example, is encouraging, and the acknowledgement I think implied in the bill as well that the Delaney clause is an unrealistic and unnecessary means of ensuring safe food is also encouraging. That requirement is a zero risk standard. It may sound good, but from a practical standpoint it is not very realistic as a standard.

The fact is that some carcinogens occur naturally in foods, but the level is so low that there is statistically no risk of cancer to anyone who consumes those foods. Consequently, to require a zero risk standard is to be more stringent than nature is itself in the production of food.

I compliment the chairman on his leadership in directing attention to problems like this, and I want to be a part of the effort that the committee is making to ensure that American foods that are available to consumers in this country are the safest possible.

I am encouraged when you look at comments that have been submitted to the committee. I think already in the record, Dr. Everett

Koop, our former surgeon general, states in a comment for the hearing record, and I'll quote: "There is no scientific evidence showing that residues from the lawful application of pesticides to food have ever caused illness or death."

I understand that already one of the witnesses has talked about the problems that have been caused that have come to his attention because of illegally applied pesticides. That's not something that is addressed by this bill. We are not talking here today about trying to deal with that. Those are already illegal applications and illegal uses which would be sanctioned under current law, not this legislation.

So I hope that what we try to do is keep our attention focused on the issue before the committee, and that is the legislation and what we are seeking to do to improve the possibility for making safe American food even safer.

The CHAIRMAN. Fine. We'll be glad to receive those questions and include the statement in its entirety.

Senator Simon.

Senator SIMON. Thank you, Mr. Chairman.

First, just so I understand, Professor Wargo, when you say "multiple U.S. average" for apple juice, 14.9, for instance, that means that an infant consumes 14.9 times as much as the average citizen; is that correct?

Mr. WARGO. That is the result of the 1977-78 food consumption survey, which basically means that in 1977 and 1978, the children who were surveyed at that time on average consumed that amount more than the U.S. average.

Senator SIMON. You both referred to the National Academy of Sciences committee report. When is that going to be coming out?

Mr. WARGO. My best guess now is sometime early in the winter.

Senator SIMON. In response to Senator Dodd's question, you both talked about having a priority of a dozen things that are really consumed. And you also talked about the Rube Goldberg structure that we have. Right now, how do we get that decision made? Who makes that decision?

Mr. WARGO. Well, my guess would be that EPA would make that choice; that they would decide to regulate not chemical by chemical. I may be wrong. You could ask Linda Fisher that question. But my sense is that if they wanted to regulate many chemicals at the same time, they could do that. They could establish a multichemical priority list and multifood priority list.

Senator SIMON. I know this is going out of order, Mr. Chairman, but Linda Fisher is right back there. This makes so much sense to me. Is this something that EPA can do, and something that we don't need to be directed by statute to do?

Ms. FISHER. Thank you, Senator. It is intuitively a very good idea, but it is a very difficult one. Two points. First of all, in 1988 the Congress passed amendments to FIFRA which put the agency on a very strong timetable to regulate chemicals, so over the next 10 years we will be getting a lot of data on all the chemicals that are currently in use. So we are kind of bringing together the review of all these pesticides in, I think, a pretty prompt time frame, much quicker than we've ever dealt with them before.

In meeting those time frames, we have already started requesting data from the chemical companies, and we have established a priority. For instance, the first target chemical group were the food use chemicals. There are about 194 of those. They are called the "List A" chemicals. Within that, each chemical is on a little bit different time frame mainly because of the data and the amount of tests that are required to be done. So for instance, for one chemical that we have a lot of data gaps, it may take three or 4 years for the chemical companies to perform the necessary tests. That means decisions on those chemicals will be a little bit more delayed.

So we have tried to set some priorities. We have focused on food use. But there are some problems that we are going to run into just in terms of getting the information we need to make decisions.

Senator SIMON. But when you say you focus on food use, are you focusing on those that are most used?

Ms. FISHER. Within the food use category, we have not necessarily set a priority. Again, part of it depends on when the information will come to us to make a decision. So we have not looked to see what is used most on apples versus milk, or that would show up in milk or something else.

Senator SIMON. I think this just makes an awful lot of good sense, and I would simply urge that what is used the most be determined, and then let's make a priority out of those things. Let's move in that direction. It doesn't mean you don't continue your studies in the other things.

Ms. FISHER. We can try to do that. The information is probably our biggest challenge to do that.

Senator SIMON. All right. Maybe between EPA and the National Academy of Sciences Committee somehow we can get that information together. OK. Thank you.

I have just two other questions. Dr. Jackson, you mentioned going to a migrant camp, and three people were sick from some chemical. Has that been reported to someone, or is it required that it be reported?

Dr. JACKSON. There is what is called the Pesticide Illness Surveillance System, which is in place in the Federal Government. California has had a much more stringent and aggressive one than what exists in the rest of the country. In fact, we report about half the pesticide poisonings in the Nation because such episodes are aggressively reported. In fact, doctors are fined if they fail to report pesticide poisoning.

Several other States have obligatory reporting laws where they are tracked down. But in general the surveillance, particularly in some States, for worker illnesses is very, very poor.

If I may, I just want to come back to Senator Cochran's point. I had pointed out that illness episodes in the past, yes, had been due to illegal uses—the watermelons—but I guarantee you if a press release had gone out saying if you think you had gotten sick from a banana, and 10,000 or 100,000 bananas arrived at EPA's doorstep for analysis, that we would have found illness associated with residues in bananas. It just would be a dumb way to detect the cases. It makes much more sense just not to have the problem, to prevent the stuff from being there in the first place.

Senator SIMON. But if I can get back to my question, right now the option is with the State?

Dr. JACKSON. The Federal Government runs the system, but its penetration into the various States is very variable. Some States do it well; some States don't do it at all.

Senator SIMON. So that we ought to be looking at strengthening that.

Dr. JACKSON. I would agree with that. In fact, if I may, the National Institute of Occupational Safety and Health has a project in place called the "Sensor Project" where they are trying to beef up the tracking down of pesticide illness cases because for every severe episode, there are many more that are much more subtle that really could be prevented at the same time.

Senator SIMON. Professor Wargo, you said we have a terrible structure, one that needs to be centralized. I have just one very simple question: Who takes charge in the centralization?

Mr. WARGO. In my mind, the leadership in this area is found inside EPA. They have the expertise to design the consumption surveys. They have the expertise in the area of chemical residues. This fragmented, as Senator Dodd paraphrased me, "disjointed incremental regulatory approach" is going to be a very difficult maze to work out of unless centralization occurs.

Senator SIMON. Thank you.

Thanks for excellent testimony.

The CHAIRMAN. Dr. Jackson, Senator Cochran isn't here, and I don't know whether there is any comment you wish to make in terms of Dr. Koop's statement.

Dr. JACKSON. I agree with Dr. Koop that in general the food supply is safe. I think that commercial aircraft is safe, but no one is saying that it couldn't be better. And I think that is what this bill is after, is to make it better.

The CHAIRMAN. OK. We'll probably have some additional questions, and we'll try not to overburden you, but we hope to be able to take advantage of your expertise as we move the legislative process forward.

We thank you very, very much. Your testimony has been enormously helpful.

Our second panel is comprised of Linda J. Fisher, assistant administrator of the Office of Pesticides and Toxic Substances at the EPA; Fred R. Shank, director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration, and Daniel Haley, administrator of the Agricultural Marketing Service, Department of Agriculture.

We'll start off with Ms. Fisher.

STATEMENTS OF LINDA J. FISHER, ASSISTANT ADMINISTRATOR, OFFICE OF PESTICIDES AND TOXIC SUBSTANCES, U.S. ENVIRONMENTAL PROTECTION AGENCY, WASHINGTON, DC; FRED R. SHANK, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, WASHINGTON, DC; AND DANIEL D. HALEY, ADMINISTRATOR, AGRICULTURAL MARKETING SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Ms. FISHER. Thank you, Mr. Chairman.

I am pleased to have the opportunity to appear before the committee today to discuss your bill dealing with pesticide and food safety.

The administration has made food safety a priority, and we strongly support legislation to effect the President's seven-point food safety plan. It has long been a priority of yours and the other members of this committee, and I do appreciate your continued interest in trying to improve the laws that govern this issue.

Our approach to the legislation does differ from yours in several important respects, and I'd like to focus both on the differences as well as the similarities.

Although we differ on our approach to risk standards, there are certain important areas of agreement. Your bill and the administration approach both replace the Delaney clause with a uniform negligible risk standard. The general safety clause of your bill requires that a tolerance be reasonably certain to cause no harm to human health, and that is essentially consistent with the administration approach to food safety.

The bill's basic requirement for negligible risk, or one in one million for carcinogens and a 100-fold safety factor for threshold effects, while too inflexibly applied, do not differ drastically from EPA's current standard practice.

In the great majority of cases we do regulate cancer risks near one in one million, and we do apply a 100-fold safety factor to protect against other risks.

The problem we see is that under your bill the actual risk standards could end up being far more stringent in practice than they appear. In other words, while the bill seems to establish a risk level of one in one million, it could force EPA to regulate at an actual level of one in 100 million or lower. This is because of the bill's various provisions on risk assessment and risk management, that are both highly restrictive and cumulative.

Specifically, the bill's exposure provisions require us to use only full tolerance values, which tend to be much higher than actual residues in calculating exposure. This assumption alone could lead to an overstatement of risk by 10- to 100-fold.

In addition, the bill's treatment of childhood exposure would make the risk standard even more restrictive. Under EPA's current approach we do take into account the fact that children eat more of certain foods and more per pound of body weight than adults do, and therefore can be more highly exposed during their first 5 years of life. This does weigh heavily in our risk assessment calculations and in our regulatory decisions.

Under your approach, we would have to go even further and limit risk for each of the first 5 years to one-seventieth of one in one million. For a given pesticide, this added limitation could make the standard two to ten times more stringent.

We recognize that the bill seeks to achieve two worthy goals in protecting children and in improving the quality of our databases, and here again the administration supports the goals but takes a different approach to meeting them.

We now take children's higher exposure into account in our risk assessment and our decisions, and we have asked the National Academy of Sciences to advise us on whether our process is protective enough. We are unsure as to the scientific merit of the year-by-year approach set out in your bill, but perhaps the National Academy of Sciences report will shed some light on this as well.

We also agree that food consumption data on which we base our decisions needs to be stronger than it is today, and we are working with FDA to improve it.

The administration approach to the FFDCA amendments also contains two important elements which are not reflected in your bill. First, we believe that the benefits of the use of a pesticide should be considered along with risks in setting tolerances provided that any tolerance we set is protective of public health.

Second, the administration has proposed national uniformity for pesticide tolerances that are set prospectively and on the basis of a complete data set.

The President's food safety plan also contains a number of key amendments to FIFRA which would make our pesticide regulatory program far more effective. We propose to strengthen FIFRA's provision to suspend and cancel pesticides, strengthen our enforcement authorities and provide better interagency consultation as well as a periodic review for pesticide registrations. FIFRA needs these changes if we are to address pesticide and food safety issues.

There are also additional portions of your bill which we support. It does clarify several EPA authorities and improves current procedures. The deadlines for review of existing tolerances are also in general accord with our registration scheduled under FIFRA 1988, although I think it is important to point out that we have already raised to the Agriculture Committee the fact that our resource constraints may threaten our ability to meet the FIFRA 1988 deadlines.

In sum, the administration approach to pesticides and food safety does differ from those provided in your bill in several important respects. We do, however, believe that legislation in this area is essential, and we do look forward to working with you and other members as we address this issue.

Thank you.

[The prepared statement of Ms. Fisher follows:]

PREPARED STATEMENT OF LINDA J. FISHER

I appreciate the opportunity to testify before you this morning on the need for legislation that will effectively address important issues related to pesticides and food safety. Clearly, food safety is a priority matter for U.S. consumers, and public interest in these issues remains high. Food safety has long been a high priority for this Administration, and we are continuing our efforts to make the U.S. food supply—already one of the safest in the world—even safer.

Those of us involved in pesticide regulation and food safety matters share some common legislative goals. We want to maintain and enhance food safety and consumer confidence in the food supply. We want to ensure that our regulatory decisions are sound, timely, and reflect the best, most up-to-date science. We also want to ensure that the laws governing pesticide regulation and use can be administered and enforced in a consistent and efficient manner that protects public health and the environment. Legislation that advances these objectives will help ensure that U.S. consumers will continue to enjoy a safe, wholesome, abundant and economical food supply.

The Environmental Protection Agency (EPA), working in concert with the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services and its Food and Drug Administration (HHS/FDA), is taking steps to achieve these ends within the constraints of current law. But existing statutes are far from ideal.

To be effective, regulatory agencies require workable statutes that give us both the authority we need to make sound decisions based on the best available data, and the tools we need to enforce our regulatory requirements. The Administration believes that new legislation amending both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIF) is necessary to advance our efforts. Obviously, we are not alone in thinking that improvements are needed. We want to work with Congress to enact effective, workable legislation that will allow us to make further progress, bringing our pesticide laws more in line with current science and providing a framework for continuing progress in future years.

We are concerned, however, that as currently drafted, certain key provisions of S. 1074 have the potential to cause serious disruption that cannot be justified in terms of anticipated food safety or public health gains. Our principal concerns relate to the overly stringent standards set for risk management decision-making; the effect of these standards in terms of exacerbating inconsistencies between FIFRA and FFDCA; the omission of benefits considerations in the tolerance-setting process; the lack of any provision for national uniformity of tolerances; and the inflexibility of provisions that prescribe how EPA must conduct risk assessments.

I want to discuss each of these issues this morning and describe how EPA believes our common legislative goals can be addressed most effectively. As legislative consideration proceeds, I hope we will be able to make constructive progress toward the development of the kind of legislation that will best serve the public interest and lead to meaningful improvements in how pesticides are regulated.

STANDARDS FOR RISK ASSESSMENT AND TOLERANCE SETTING

As I indicated earlier, we are concerned that the laws under which we regulate pesticide use work together efficiently. Central to our concern is the need for compatible standards to guide our decision-making under both FIFRA and FFDCA. As you know, one critical point is how the 11zero-risk" standard of the Delaney clause of FFDCA can be reconciled with the risk-benefit balancing approach embodied in FIFRA. The Administration strongly supports legislation that will bring the standards for pesticide regulation under FIFRA and the FFDCA into greater harmony by eliminating the Delaney clause and establishing one consistent standard for negligible risk.

One area where we have reached some consensus with the sponsors of the legislation before your Committee is that a "zero risk" approach to regulating substances that may be associated with cancer in laboratory animals is no longer appropriate. We support the bill's elimination of the literal "zero risk" provisions of the Delaney clause and the establishment of a negligible risk standard. However, the standards that S. 1074 would put in place of the clause raise new problems.

A major area of concern relates to the risk standards that the bill establishes. The Administration supports legislation that will harmonize the inconsistent standards that now apply to pesticide residues on raw and processed foods and establish a single, protective standard for all residues in food. We interpret S. 1074's statement of the general safety standard, a reasonable certainty of no harm, as a positive step in this direction.

For cancer risks, regulatory agencies like EPA have adopted conservative carcinogenic risk assessment techniques that allow us to extrapolate from high dose animal bioassays to the expected lower levels of human exposure. Generally, we have regarded carcinogenic risks in the range of 10 to the minus 6th—or an upper bound increase in lifetime risk on the order of one in one million—as negligible, i.e., not of significant regulatory concern. Both EPA and FDA have accepted this benchmark,

while noting that the imprecision inherent in the assumptions generally made in our risk assessments, and the relative strengths or weaknesses in the underlying data, militate against the false sense of precision implied by adoption of a "bright line" standard such as one in one million. We believe risks in this range, estimated using our current risk assessment methodologies, clearly meet or exceed the bill's general safety standard of "reasonable certainty of no harm.

At first blush, S. 1074 appears to accept 1 x 10 to the minus 6th as an appropriate safety standard for pesticide residues in food. Upon closer examination, however, the bill prescribes such rigid assumptions in the calculation of risk estimates, particularly in terms of how EPA must assess exposure, that the net effect is to establish a much more stringent standard, perhaps as much as several orders of magnitude more conservative than 10 to the minus 6th. Even if EPA had sound data that would enable us to refine our exposure analyses and arrive at a more realistic estimate of risk, S. 1074 would not allow the Agency to use many types of data we now rely on in making tolerance decisions.

For example, EPA's current practice in its initial estimation of exposure for chemicals that raise chronic toxicology concerns (such as carcinogenic risk) is to assume that all pesticide residues are present at tolerance levels on foods for which there are tolerances, unless we have empirical data (e.g. from "market basket" or supermarket surveys) that more closely represent actual dietary exposure. We recognize that using this "theoretical maximum residue concentration" (TMRC) in most cases significantly overstates actual risk, in a number of instances by factors of 10 to 1000.

If there are no apparent risk concerns assuming worst case scenarios, we will generally proceed no further with our exposure analysis. If there are potential concerns, we will seek to obtain additional information to more accurately refine our exposure estimate. This information includes data on average field residues; percent of crop treated; actual residue levels in food at the time of sale; chemical degradation over time; or the effects of processing, washing, peeling or other food handling and storage practices.

As we read the terms of S. 1074, EPA would no longer be able to use most of these types of data in risk assessment. The only adjustments to our worst case scenarios would be for percent of crop treated (in certain limited circumstances), and for the effects of food processing to the extent that EPA could use data from processing studies to establish separate tolerances for processed foods at a lower level. Data on residue levels at the point of sale of food could not be used. Nor would S. 1074 allow EPA to consider information indicating that pesticides may be used less frequently and at lower application rates than permitted by the label, or that residues decline over time. EPA could not consider the fact that residues from even the highest application rates are, on average, 3 to 5 times lower than tolerance. (This is because the Agency's practice is to set tolerances at levels designed to ensure that farmers who use pesticides in accordance with EPA-approved labeling will not be subject to product seizures or other enforcement actions.)

The effect of these proposed statutory constraints on calculating exposure is significant. It could transform the nominal standard of 10 to the minus 6th into a standard of perhaps 10 to the minus 7th to 10 to the minus 8th or more over a lifetime. Other provisions defining the negligible risk standard, and prescribing the assumptions that EPA must make, could further exaggerate the calculation. Notably, provisions establishing a second risk standard for nonthreshold effects based on exposure to young children and data requirements for subgroup analyses compound the effect. These provisions are discussed in greater detail later in my statement. The overall result of compounding all of these assumptions and standards would force the Agency to regulate at levels that would eliminate many pesticide uses, without achieving meaningful incremental reductions in risk.

The bill's provisions for establishing tolerances for chemicals that induce "threshold" effects for which EPA has identified an apparent "no observable effect level" (NOEL), need flexibility. The Agency generally uses an uncertainty factor of 100 when extrapolating from animal data. However, there are situations in which a smaller uncertainty factor can be justified on the basis of scientific data. For example, if we know that humans and the tested species react in much the same way at the same dose, there may be no need for the full order of magnitude uncertainty factor commonly used to allow for between-species differences.

A final concern in terms of the risk standards imposed by S. 1074 relates to the treatment of chemicals that may induce non-cancer, non-threshold effects. The bill places any toxic effect for which EPA has not established a NOEL, or apparent threshold dose, into the same category as carcinogenic effects. Such effects include

idiosyncratic reactions and other effects, such as mutagenesis, for which we are not always able to identify a NOEL.

The techniques used in carcinogenic risk assessment and the associated 10 to the minus 6th benchmark figure were developed over the last 15 years or so, based on conservative methods of extrapolating data from high dose animal bioassays to lower dose human exposures and the default assumption that all carcinogenic responses are without an apparent threshold. The resulting numbers do not represent actuarial risks, but theoretical upper bound projections based on protective assumptions about carcinogenesis.

The original techniques developed for assessing potential carcinogens may have no scientific validity if applied to other effects. In fact, we are beginning to suspect that these methodologies may be inappropriate for certain specific carcinogenic responses.

Although we recognize the need to rigorously regulate for these types of health effects, carcinogenic risk assessment techniques are not appropriate for the assessment of these types of risks. EPA must have flexibility to evaluate potential idiosyncratic reactions and other effects for which no clear dose-response or NOEL can be described. The science for studying and assessing non-cancer effects must be given the opportunity to develop, and not forced indiscriminately into the cancer mold. Neither of the two categories in S. 1074 is necessarily appropriate for these kinds of risks, and therefore we suggest the Agency be allowed flexibility in dealing with non-cancer, non-threshold effects.

One of the major criticisms of a literal approach to the Delaney clause in recent years has been that it tended to "freeze the science," making it difficult for EPA to use the latest advances in our understanding of risk assessment and carcinogenesis in regulatory decision-making. S. 1074 should be amended to delete provisions which could have the effects of freezing scientific risk assessment and retarding EPA's ability to reflect advances in scientific understanding of both cancer and non-cancer effects in our regulatory decisions.

PROTECTING CHILDREN FROM PESTICIDE RISKS

S. 1074 places particular emphasis on infants and young children. Clearly, we at EPA agree that our tolerance decisions should ensure that no element of the population, including the very young, is subject to unreasonable risk from dietary exposure to pesticide residues. The provisions included in S. 1074, however, impose new standards that, while aiming at a commendable goal, go beyond what can be justified in terms of current science. Particularly when placed on top of other provisions of the bill, the compound effect of these provisions would be an overly rigid, overly stringent standard for tolerance setting.

As we have already discussed, S. 1074 sets a nominal overall risk standard for cancer and other non-threshold effects of 10 to the minus 6th. In addition, the bill would require a second standard to be met, "one in a million divided by 70 for any single year of exposure during the first 5 years of life." As a practical matter, for many if not most foods eaten by children, this second standard will drive the tolerance decision. Again, the effect is to go beyond the nominal 10 to the minus 6th standard, making it 2 to 10 times more stringent, depending on how commonly the food is consumed by children. The reason for this is that children, in general, consume proportionally more food for their size than adults.

EPA has historically paid particular attention to potential effects on children in our regulatory decision-making. We pioneered the concept of assessing risks by age group. Our DRES subgroups include nursing and non-nursing infants less than 1-year old; children in the age groups 1–6 years and 7–12 years; adolescents 13–19 years (males and females separately); and nursing and pregnant females. Routinely, in assessing pesticide risks, we evaluate children's proportionally higher exposures. EPA will take regulatory action when data exist to indicate that children may be particularly vulnerable to adverse effects; examples include our lead strategy and the establishment of maximum contaminant levels for nitrates in water supplies.

EPA is also taking steps to increase our scientific understanding of factors that may make children more, less, or differentially susceptible to adverse effects, and how best to evaluate dietary risks to this special population group in our pesticide regulatory decisions. The National Academy of Sciences (NAS) is conducting an ongoing study for EPA on this issue, and we expect to receive the report early in 1992. Our food safety laws must provide the flexibility EPA will need not only to act appropriately on the NAS recommendations, but also to adapt our policies in the future as new knowledge is developed.

At this time we know of no valid scientific basis for S. 1074's special risk standard of 1/70th of 1 in a million for each of the first 5 years of life. It appears to be based on an assumption that children are, in all cases, more sensitive to nonthreshold effects than are adults. To date, the science simply does not support such an assumption. The limited data available indicate that in some cases there may be greater sensitivity; in some cases children may be less sensitive, (for example, due to their higher metabolic rate); and in still other instances children may respond in a manner completely different from adults. In any event, differences in sensitivity are not likely to be as significant as differences based on the relatively larger quantities of food children consume for their size, an effect EPA does take into account.

A second provision aimed at children is the requirement for data on exposure/consumption for the age groups 0–1 year, 1–2 years, 3–4 years, 4–5 years, 6–10 years, and 11–18 years. As discussed below, the Dietary Risk Evaluation System (DRES) does not now provide breakdowns for all of these subgroups, and there are likely to be too few observations in the individual year-by-year age categories for a number of foods. We are unsure of the value of requiring such specific information on narrow age groups, and as stated above, we believe it could potentially have an adverse effect on the food supply.

BENEFITS CONSIDERATIONS

A third major focus of concern regarding S. 1074 is the lack of any provision allowing consideration of the benefits of pesticide use in tolerance setting. EPA strongly supports a change in the law to allow consideration of benefits in all tolerance decisions, provided that any tolerance we set must protect the public health. Under current FFDCA, benefits are considered in the establishment of tolerances for pesticide residues on raw agricultural commodities as required by the law's provision that we take into account the need for the production of an "adequate, wholesome, and economical food supply." While we will only set tolerances which we believe are protective of the public health, our decisions reflect consideration of the overall societal benefits of a pesticide's use. Failure to continue this policy only exacerbates the existing inconsistencies between our two key pesticide regulatory statutes, FIFRA and FFDCA.

IMPROVING THE DATA BASE FOR REGULATORY DECISION-MAKING

A recurring theme in S. 1074 is the need to improve the data bases underlying EPA's pesticide tolerance decisions. Here, too, we are in agreement on the fundamental principles: we do need better data, especially as we continue to consider population subgroups in performing our analyses of potential pesticide risks. When we turn to considerations of practical implementation, however, the specific provisions of S. 1074 raise some concerns.

We need to focus on the issue of what data can reasonably be expected to be obtained and what incremental benefits can reasonably be anticipated from their use. As currently drafted, for example, S. 1074 contains provisions that require EPA to have "reliable, statistically significant data regarding the dietary exposure to persons who have consumed the food for which the tolerance for the residue is proposed or is in effect," at a minimum for each of a number of age groups listed in the bill. If there are too few observations in any category of consumers (say, squash eaters aged 1–2 years) to qualify as "reliable, statistically significant data," then apparently no tolerances could be set for any pesticide on that food.

EPA's current practice is to use the ORES to assess potential exposure to the population as a whole as well as appropriate subgroups. ORES currently allows us to look at over 20 subgroups as well as the general population when considering tolerance decisions. The data in DRES are drawn from the Nationwide Food Consumption Survey conducted by USDA, and include approximately 88,000 data points, based on a one-day recall and 2-day food diary survey of 30,770 respondents. Even with this data base, some foods may not be eaten frequently enough by enough respondents in a given subgroup to meet a rigorous test of "statistical significance" of representativeness.

EPA should have the flexibility to make reasonable "default" assumptions about exposure when necessary. S. 1074 as introduced would not allow EPA to use available data and reasonable default assumptions.

We are particularly concerned about the possible impact of these provisions on the ability of growers to produce fruits and vegetables. Fruits and vegetables generally represent relatively "minor uses" of pesticides. Already, pesticide manufacturers have abandoned a number of these minor uses, rather than generate the data

EPA is requiring as part of our reassessment of older pesticides under amendments to FIFRA enacted in 1988. The cost of data generation do not appear justified to the registrant in terms of expected revenues from pesticide sales for minor uses. Enactment of legislation that imposes significant new data requirements could exacerbate the minor use problem, at a time when health authorities are urging Americans to increase their consumption of many of these foods.

In summary, while we agree that improvements to DRES are needed, EPA does not believe that all of the new data requirements in S. 1074 are justified, when reasonable default assumptions will protect the public health. We have undertaken development of a number of DRES enhancements; for example, we are developing the capability to estimate the standard error of the mean consumption, which will help us evaluate when there are too few data points in the food consumption survey to make a reliable estimate of exposure. We will continue to work to develop sound approaches that will enhance our data bases.

UNIFORMITY OF TOLERANCES

S. 1074 fails to establish national uniformity for pesticide tolerances. Without such a provision, states could set tolerances for pesticide residues in food that vary from those established by EPA, regardless of whether there were sound environmental or public health reasons for the differences. This situation creates the potential for considerable consumer confusion and disruption of interstate commerce in food products, if our food distribution and marketing systems must cope with a patchwork of inconsistent state-by-state requirements. Inconsistent tolerances could also complicate international trade in raw agricultural commodities and processed food.

The Administration has proposed that national uniformity be established by statute on a strictly prospective basis, for tolerances that are set as a result of EPA's ongoing reregistration efforts, and for new pesticide tolerances established based on complete data and in accordance with the updated standards for tolerance setting that we have proposed. Under our proposals, there would be a presumption in favor of uniformity, but states would still be able to obtain waivers and establish their own tolerances if special local circumstances exist. In addition, EPA would have the option of revising the national tolerances on the basis of a State's proposal for more stringent limitations, thus enhancing food safety for all Americans.

OTHER PROVISIONS

I would like to comment briefly on certain other issues raised by the bill.

First, we believe the deadlines and requirements imposed by S. 1074 may raise resource concerns for EPA that are not fully alleviated by the inclusion of a fee provision. As you know, under the FIFRA amendments passed by Congress in 1988, we are requiring up-to-date data and reevaluating all of the older pesticides first registered before many of our current scientific data requirements were in effect. FIFRA '88 placed this reregistration program on a series of strict deadlines. We appreciate the fact that S. 1074's deadline provisions are much closer to the FIFRA '88 schedule than the comparable provisions of previous food safety bills. As we have testified before the House Agriculture Committee, however, resource constraints threaten EPA's ability to meet the FIFRA '88 deadlines. Moreover, S. 1074 would greatly expand the number of chemicals subject to review by adding inert ingredients and newer food use active ingredients.

Second, the bill contains a new provision that would shift the burden of proof in certain judicial proceedings to EPA. It is not completely clear what this change is intended to accomplish. Under existing law, of course, EPA decisions are already subject to judicial review. The proposed change appears out of step with long-standing principles governing judicial review of regulatory decisions based on complex scientific data, and we believe it is not appropriate in this case.

Finally, we support a variety of provisions of the bill which clarify the Agency's authority in several areas and which provide a more efficient administrative process for tolerance-setting. For example, the bill provides explicit statutory authority for EPA to set expiration dates for tolerances; to require data; to reevaluate existing tolerances and exemptions; to demand practical methods of residue analysis; to collect fees for the maintenance of tolerances; and to allow food containing residues from legal uses of pesticides to clear the channels of trade after a tolerance has been reduced or revoked.

THE ADMINISTRATION'S FOOD SAFETY PLAN

I'd like to turn now to a brief discussion of the Administration's Food Safety Plan, as developed and submitted to the Congress during the last session.

Two of our key goals in the food safety plan are to bring FIFRA and the FFDCA into greater harmony and to enhance our ability to take prompt, effective action when we find that a pesticide poses unreasonable risk. For these reasons, we believe it is imperative that we work to amend both statutes.

I have already covered our two major FFDCA proposals. First, we support enactment of legislation that would establish a single, protective standard for the establishment of tolerances for pesticide residues in foods, eliminating the obsolete Delaney clause standard and introducing the concept of negligible risk in a way that will permit future advances in our scientific understanding to be reflected in our regulatory policies. EPA would assess both risks and benefits in making tolerance decisions under the FFDCA and registration decisions under FIFRA. We also proposed to amend FFDCA to establish, prospectively, national uniformity for tolerances that EPA sets or reaffirms based on a complete data set, pre-empting inconsistent State standards except where a waiver is justified based on special local circumstances.

Our proposed FIFRA changes would enable EPA to use its suspension authority more effectively when the data warrant immediate suspension of pesticide use; streamline the time-consuming cancellation process; establish the principle of periodic review of pesticides to ensure that the data supporting registration are regularly reviewed against current scientific standards; strengthen our enforcement authorities; and increase penalties for FIFRA violations. Finally, the Administration plan provides for enhanced interagency consultation among EPA, USDA, and HHS on pesticide, public health, and food safety issues.

The Administration continues to support enactment of food safety legislation that addresses each of these points. We recognize that the approach we have outlined, amending both FIFRA and FFDCA, complicates consideration in a jurisdictional sense, but we urge you and your colleagues on the Agriculture Committee to join with the Administration in working toward comprehensive legislation.

CONCLUSION

EPA supports enactment of strong food safety legislation that will update and upgrade our authorities under both FFDCA and FIFRA. We cannot, however, support enactment of S. 1074 as currently drafted.

Taken together, the provisions of S. 1074 significantly restrict flexibility in using the best available scientific data and information in regulatory decision-making, and may inhibit scientific progress. The net effect of eliminating all benefits considerations and compounding the many conservative assumptions required by the bill would produce an unnecessarily stringent system of regulation. In that sense, its actual implementation may in fact be more stringent than under current law with the Delaney Clause. Many important pesticide uses could be lost, for no meaningful' public health gain.

For these reasons, we urge that S. 1074 in its current form not be enacted. We stand ready to work with you toward the development and passage of food safety legislation that addresses the important issues I have outlined in a more workable and effective way. Building on some of the themes contained in your legislation, as well as the key points of the Administration's food safety plan, we can act together to make significant improvements in our current system of pesticide regulation.

This concludes my statement Mr. Chairman, I would be pleased to answer any questions that you or the other members of the committee may have.

Senator SIMON [presiding.] Thank you.

Fred Shank, director of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration. We are pleased to have you here, Mr. Shank.

Mr. SHANK. Good morning, Senator.

I appreciate the opportunity to testify today on S. 1074, the "Safety of Pesticides in Food Act of 1991".

FDA has long been a leader in food safety. We have been in the forefront in making estimates of exposure and using contemporary

scientific knowledge to assess the risk of chemicals added intentionally or inadvertently to foods.

For many years, we have collected data on the incidence and levels of residues. The high quality and consistency of our analytical results as well as the sensitivity of our analytical methods in detecting and measuring residues in the parts per billion range are recognized worldwide.

We are further strengthening our pesticide program in line with the "Pesticide Monitoring and Improvements Act of 1988". We believe the committee has in S. 1074 identified several of the areas in the regulation of pesticide residues that are in greatest need of reform, such as the application of a negligible risk standard to the pesticide residues in both raw and processed foods.

This and other issues were part of the administration's food safety plan announced by President Bush in 1989.

While we applaud the opening of the food safety debate, in this case, legislation pertaining to pesticide residues, we have serious concerns about the impact of the legislation generally as well as several concerns specific to FDA's program.

S. 1074 would update the statutory safety standard applicable to carcinogens by applying the concept of negligible risk to pesticide residues on both raw agricultural commodities and processed foods. And we support the use of this concept as the basis for establishment of pesticide residue tolerances, but we believe that there are serious drawbacks to the bill's highly prescriptive, very conservative approach and procedure for risk assessments. My written remarks elaborate on these issues.

We are also concerned that S. 1074 would require FDA to concentrate the bulk of its monitoring effort and existing resources on relatively few chemicals. The bill seems to suggest that pesticides for which tolerances have been established pose the greatest public health risk and thus warrant the greatest monitoring effort. Our monitoring data over the years have shown that tolerances are rarely exceeded. Indeed, the vast majority of the illegal pesticide residues that we detect each year involve the pesticide residue-food combinations for which a tolerance has not been established.

Residue data generated by the States and collected into an FDA-funded database show very much the same thing, that is, very few residues exceed the tolerances.

We are also concerned that S. 1074 would appear to give lower priority to monitoring of residues resulting from misuse and monitoring for pesticides that are used in other countries, but not in the U.S. Indeed, we agree that food safety law reform with respect to pesticides is warranted. Further, we join EPA and USDA in the belief that rational, comprehensive food safety reform requires amendments of both the Food, Drug and Cosmetics Act and FIFRA.

However, in accomplishing the reform, flexibility must be preserved for the regulatory agencies to use the latest scientific knowledge and judgment in arriving at food safety decisions. In other words, we urge that legislation outline the framework, but not prescribe a recipe for food safety.

We stand ready to work with committee staff to develop effective, workable legislation that will bring our pesticide laws into

line with the current science and provide a framework for continuing progress in the future.

Senator, we commend the committee for opening the discussion on these vital issues and thank you for affording us this opportunity to testify.

[The prepared statement of Mr. Shank follows:]

PREPARED STATEMENT OF FRED R. SHANK, PH.D.

Mr. Chairman, I appreciate the opportunity to testify today on S. 1074, the "Safety of Pesticides in Food Act of 1991." This legislation would revise the authority of the Environmental Protection Agency (EPA) under the Federal Food, Drug, and Cosmetic Act (FDC Act) to regulate pesticide residues in food. The bill would also have both a direct and an indirect impact on the programs of the Food and Drug Administration (FDA).

EPA, FDA, and USDA share responsibility for the Federal regulation of pesticides used on food or feed. EPA registers pesticides for use and establishes tolerances, which are the maximum amounts of residues that may legally remain in or on a food when a pesticide chemical is used according to label directions. FDA enforces compliance with EPA's tolerances by sampling and analyzing both domestic and imported food to determine whether any pesticide residues remaining in or on the food conform with established limits. USDA carries out this function for meat and poultry products.

FDA has watched closely and participated in the debate on regulation of pesticides that has occurred over the past several years in Congress as well as in the public arena. Moreover, FDA has long been involved in the broader issues of food safety. Indeed, although we agree that food safety law reform with respect to pesticides is warranted, we caution that this effort not divert attention from other food safety problems, such as microbiological hazards, which equal or exceed the risks posed by pesticide residues.

This debate over regulation of pesticides has generated a wide range of proposed revisions to food safety law, but also has highlighted some areas of general agreement. For example, there is agreement about the need to streamline the process for taking regulatory action against pesticide registrations and associated tolerances for pesticides about which serious safety considerations have arisen, and for harmonization of discrepancies in current law.

As you may recall, in October 1989, President Bush urged that changes to food safety law include improvements to enhance EPA's authority to suspend pesticide use; streamline cancellation procedures; establish periodic review of pesticide registrations; increase consultation among the agencies having responsibility for regulating pesticides; strengthen EPA's enforcement authorities; eliminate inconsistent standards for pesticide residues in raw and processed foods through implementation of a "negligible risk standard;" and establish prospectively, national uniformity for pesticide tolerances. S. 1074 also addresses several of these points.

FDA is keenly aware that absolute safety can never be guaranteed. The role of Federal agencies must be to assure that agricultural pesticides pose no unreasonable risks, to set protective limits for pesticide residues, and to enforce these limits. Through proper risk assessment and risk management, risks can be reduced to insignificant or "negligible" levels.

We, therefore, believe that any changes to the existing statutory framework for pesticide regulation should be consistent with current scientific principles and public health goals, be flexible enough to allow regulatory decisions to reflect advances in scientific understanding, and be enforceable. The latter can be accomplished only if Federal regulatory agencies are provided with adequate tools to do the job.

We have serious concerns about the impact of the legislation generally, as well as several concerns specific to FDA's programs.

NEGLIGIBLE RISK

As you know, under the current law, pesticides which are applied to or concentrate in processed foods are subject to the Delaney clause in section 409 of the FDC Act, while pesticide residues in raw agricultural commodities are subject to a risk/benefit determination under section 408. The Delaney clause, read literally, requires absolute safety and would prevent the establishment of any tolerance for a residue in a processed food of any pesticide that is a human or animal carcinogen.

At the time the Food Additive Amendments were enacted (1958), the Delaney clause, literally interpreted, was consistent with the scientific knowledge and technology of the day: the number of known or postulated carcinogens was fairly small, and the then state-of-the-art capability to detect a substance at a level of a few parts per million was considered ultrasensitive. As testing methods have become more sophisticated, however, it has become abundantly clear that a new approach for addressing risk is needed. Increasingly sensitive analytical methods allow detection of substances at the level of parts per trillion.

An appropriate negligible risk approach allows these scientific advances to be taken into account. FDA is quite familiar with this type of approach, as we use or have proposed its use in a number of cases. For instance, advances in risk assessment enable scientists to conclude that some substances shown to be carcinogens in high-dose animal studies represent no risk to human health when present in minute quantities in the food supply under specified conditions of use of the substances. This conclusion was also reached by the National Academy of Sciences in its 1987 report, Regulating Pesticides in Foods: the Delaney Paradox.

S. 1074 defines "negligible risk" as a reasonable certainty that "no harm to human health" will be caused by exposure to a pesticide chemical residue, thus recognizing the need to update the statutory safety standard applicable to carcinogens by applying this concept to pesticide residues. The bill also addresses the need for a consistent standard for regulating pesticide residues in both raw agricultural commodities and processed foods by applying negligible risk to all pesticide residues. While we support the use of this concept as the basis for establishment of pesticide residue tolerances, we believe there are serious drawbacks to the bill's highly prescriptive definitions of "negligible risk."

The bill differentiates between pesticide residues for which EPA can identify a level at which the pesticide will not cause or contribute to any known or anticipated harm to human health ("threshold" pesticides), and "non-threshold" substances, for which such a level cannot be identified. All carcinogens are placed into the latter category regardless of their mechanism of action. We believe that this wholesale treatment of all carcinogens as non-threshold substances is contrary to the evolving scientific knowledge about carcinogens. We believe that for some carcinogenic pesticide residues, a threshold may be identified, and that such threshold carcinogens should be regulated like all other threshold chemicals.

Another issue that we would raise as a point of general concern is found in Section 408(m) (2) (C), which would require EPA to have the burden of proof in any judicial proceeding pertaining to tolerances, including revocation or denial of a tolerance. Currently, the FDC Act requires the proponent of a food additive petition or the sponsor of a new drug to show that a food additive or drug is safe for its intended use. FDA's regulations for administrative hearings reflect this, in that the proponent of safety is required to bear the burden of proof in any administrative proceeding. We suggest that the provision be deleted.

BACKGROUND ON FDA'S PESTICIDE PROGRAM

Before discussing the rest of our concerns about the bill with respect to FDA's existing program, some general background on FDA's pesticide residue monitoring program and strategy might be helpful.

Over 300 pesticides have tolerances for use on food crops in the United States, and an additional 200-300 pesticides may be used in foreign countries. Over 100 countries export foods to the United States annually, and crops are produced in all 50 states and in U.S. territories each year. The challenge for FDA is to select from this universe of literally hundreds of thousands of possible pesticide/commodity/location combinations those which should be given priority.

The agency has developed a sampling strategy to focus its resources as efficiently, comprehensively and cost-effectively as possible. In general, the agency emphasizes commodities that have relatively high dietary importance, for example, potatoes rather than artichokes because potatoes are consumed in much greater amounts. FDA also considers factors such as the toxicity of a pesticide and its metabolites and degradation products, volume of usage, the types of crops likely to be treated, prior residue findings and violations, and state monitoring programs.

FDA routinely cooperates with EPA and includes in its sampling program chemicals identified by EPA as being of special interest. For example, FDA provides EPA with monitoring data for pesticides undergoing "Special Review," initiated when new evidence suggests that use of the pesticide may present a previously unrecognized risk.

While we are certainly aware of the need and desirability of continuing cooperation with EPA, we stress that FDA needs regulatory flexibility to determine the most appropriate sampling strategies, direct our pesticide monitoring resources in the most cost-effective, efficient manner possible, and still be able to respond in a timely fashion to specific concerns or issues that arise. The basis for sampling as set forth by S. 1074 could preclude this.

Section 408(k) of S. 1074 would require FDA to give priority to foods containing residues identified by EPA as either above the negligible risk standard, or "which may under certain circumstances reach or exceed such standard."

We are concerned with the potentially significant impact this might have on the agency's monitoring resources. Strict FDA compliance with the wording of the bill could have FDA concentrating the bulk of its monitoring effort and existing resources on relatively few chemicals.

This provision also seems to suggest that certain pesticides for which tolerances have been established pose the greatest public health risk, and thus warrant the greatest monitoring effort. Our monitoring data over the years have shown that tolerances are rarely exceeded. The vast majority of the illegal pesticide residues we detect each year involve pesticide residue/food combinations for which no tolerance has been established. We are concerned that this provision appears to give lower priority to monitoring for residues resulting from misuse and monitoring for pesticides that are used in other countries but not in the United States. We therefore question whether the monitoring priorities in the proposed bill will enhance consumer protection. We also respectfully note that Congress, the General Accounting Off ice, and others have repeatedly urged FDA to expand its sampling of imported foods. The bill's monitoring provisions appear to contradict this goal.

EXPOSURE DATA

Several sections of S. 1074 refer to "statistically significant data" with regard to estimating dietary exposure to pesticide residues. Section 408(b)(2)(E) identifies nine population groups (primarily children) for which such data are expected to be available and used by EPA in evaluating risk. While we support the intent of the bill to prevent children from bearing a disproportionate risk from exposure to residues, we question the codification of the divisions in the groups identified in the bill. Agencies need flexibility to define food consumption groupings based on valid scientific criteria.

We further question whether data regarding the food consumption patterns of groups with "special consumption patterns" are available. Given the wide range of potential diets for extant ethnic populations, vegetarians, etc., the task of evaluating dietary exposure for all these potential populations, even if the data were available, takes on monumental proportions.

METHODS OF ANALYSIS

FDA supports the concept of formal consultation with EPA to assure that an analytical method suitable for enforcement exists before a pesticide tolerance is established or allowed to remain in effect. FDA and EPA have for many years consulted on analytical methods and maintain an interagency task group, which includes representatives from USDA, for the regular exchange of information about analytical methodology. FDA agrees with the bill's proposal that analytical methods be considered early on in the tolerance setting process, and that multiresidue methods be emphasized.

We note, however, that the bill does not require EPA consultation with FDA when a method is identified under the "Special Rule" or when an analytical method is reevaluated. We see no reason for absence of consultation in the "Special Rule" situation and during the reevaluation of a method. We believe that the same level of consultation is necessary in any situation involving an analytical method that FDA may use in its enforcement program.

We are also concerned that the "Special Rule" could potentially force upon the agency an inappropriate, albeit the most sensitive, analytical method, regardless of that method's cost, complexity, or validity. The acceptability of a method should not be based solely on its sensitivity use. Moreover, the "Special Rule" provision, as written, requires only that a method detect a residue. FDA needs analytical methods capable of both detection and measurement to enforce tolerances and monitor the incidence and levels of pesticide residues.

We are also concerned that the consultation contemplated in the bill will compel FDA to conduct laboratory trials of methods.

FEES

The bill authorizes EPA to impose and collect fees related to registering and establishing tolerances for pesticides. We believe this authorization should be expanded to include the costs of the additional activities required of FDA under this bill. For example, as mentioned previously, S. 1074 would require FDA to perform monitoring over and above the Agency's regulatory program to determine if residues are in compliance, and also to evaluate the suitability of analytical methods. To carry out additional sampling and analyses and evaluate analytical methods without affecting the current program would require additional resources. We believe the costs of these additional activities should be covered by user fees.

CONCLUSION

In sum, we believe that S. 1074's incorporation of the concept of negligible risk to be a significant first step toward updating the law to reflect changes in scientific knowledge and methodologies. Rational food safety law reform is warranted in light of what we now know about chronic exposure to chemicals and the progress science has made since the Delaney clause was first enacted.

As currently written, however, we oppose enactment of S. 1074 because of the concerns outlined by the administration at this hearing. Nevertheless, the administration is ready to work with committee staff to discuss ways in which our concerns might be resolved.

Mr. Chairman, we commend the committee for opening the discussion on these vital issues, and thank you for affording us this opportunity to testify. I would be pleased to answer any questions that you or members of the committee have.

Senator SIMON. Thank you, Mr. Shank.

Next, Daniel D. Haley, administrator of the Agricultural Marketing Service at the Department of Agriculture.

Mr. HALEY. Good morning, Senator Simon and other members of the committee. I welcome the opportunity also to be with you today to present the department's views for legislative reform for our food safety laws concerning pesticides and to discuss how this reform will affect American agriculture.

My testimony will focus on certain key provisions in S.1074 which the department feels could cause dietary hardships and economic burdens for our consumers and our producers.

The judicious application of pesticides plays an important role in providing the safest, most abundant and affordable food supply of any place in the world—in fact, we are the envy of the world. Our shared goals are to ensure public health and environmental protection and maintain confidence in the safety of the food supply.

Obviously, the way we achieve that goal differs dramatically.

The food safety plan announced by President Bush 2 years ago is a comprehensive package of reforms that taken together will mark a major step forward in public health and environmental protection.

In the interest of time let me just reiterate what my colleagues have said and, consistent with the President's plan, say that we support national uniformity of tolerances prospectively; we support a single pesticide tolerance for both raw and processed foods, according to the NAS recommendation, and we support the concept of a negligible risk standard.

It should be made clear, however, that EPA can establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that the tolerance is protective of the public health—and I stress that again—protective of the public health—and that the risk is reasonable.

Consideration of pesticide benefits is, as you know, of major importance to the Department of Agriculture. Pesticides provide important societal benefits to consumers and producers. These are health benefits. These benefits are nutritional. And yes, these benefits are economic.

The loss of important food use pesticides can result in heightened risk of disease-causing organisms in food such as fungus, molds and bacteria; they can result in food price increases, adverse effects on food quality, and reduction in the availability of nutritional food choices.

I want to emphasize that these benefits should be considered. They should not drive the process. They should not overwhelm the process. But they need to be considered.

In the short time I have left, let me just take a moment and highlight an extremely important area, and that is the problems associated with pesticides for minor use crops. As a result of re-registration, many registrants who respond to the increased cost of testing and tight deadlines have canceled pesticides for numerous fruit and vegetable crops—literally thousands. These include livestock and grain uses as well. Many more uses are expected to be dropped in the near future. USDA and EPA have recognized that much needs to be done if agricultural producers are to deal successfully with the consequences of re-registration. Unfortunately, we feel that S. 1074 would exacerbate what already promises to be a train wreck for American agriculture if we don't get a handle on this.

Overall, to summarize, our concerns are basically threefold. This bill would eliminate the current system of balancing benefits of pesticides against the risks they pose to society. It would establish an unnecessarily prescriptive method of calculating negligible risks, and it would remove the flexibility to look at real residues, real exposures, and constantly react to the science in that area.

We must remember the scientific community has reiterated time and time again that minuscule amounts of pesticides in our food supply is not a problem. In addition, pesticide residues generally do not exceed tolerances according to the Food and Drug Administration or the National Research Council—in fact, just the opposite.

I'd like to take a moment if I could, Senator, to respond to several things that were discussed by the previous two witnesses. I think they said on half a dozen occasions we don't have a statistically-based information database on residues. Last year, this Congress authorized a program that we in agriculture are implementing as we speak. We are taking samples right now, not the enforcement modes of the States and FDA, but a comprehensive, statistically based sampling of those residues across this country.

We have six States that we have cooperative agreements with. We are doing it on 105 pesticide combinations. So I think we are in the process of getting that database that was said does not exist.

Another thing that was raised was that there are 105 uses for apples and 110 for citrus. That's a very good point. The fact of the matter is any given grower might use two or three or five of them, not 105 of them. And should we be regulating on what they use or the theoretical maximums that we must revert to that every, single one of those are used on an orange crop at the maximum tolerance

and consumed for 70 years. That's the kind of reality we hope to bring to the process.

One more thing in the written testimony that was raised here by Dr. Jackson, who stated that there were some 1,000 illnesses from aldicarb, confirmed illnesses. Well, I was the department official in the California State department of agriculture when that case was put to rest. I was in charge of the litigation and the settlement in that case, and nowhere did we ever have 1,000 confirmed illnesses of aldicarb. So I wanted to make that clear for the record.

In conclusion, the department does not support the prescriptive standards of S. 1074. We agree that the Federal laws on food safety and pesticide use need to be revamped so as not to severely impact the credibility of the current system and the new scientific and technological breakthroughs in the chemical industry. It is imperative that we proceed in a responsible manner and not jeopardize the Nation's agricultural industry, which represents some 20 percent of our GNP.

We urge the committee in its deliberations to consider the adverse impacts of S. 1074 on American agriculture and the consuming public.

Thank you, Mr. Chairman. That concludes my verbal statement.

[The prepared statement of Mr. Haley follows:]

PREPARED STATEMENT OF DANIEL D. HALEY

Good morning, Mr. Chairman and Members of the Subcommittee. I welcome the opportunity to be with you today to present the Department's views for legislative reform of our food safety laws concerning pesticides and to discuss how this reform will affect American agriculture. I am accompanied today by Dr. Craig Reed, Director of the Science Division, Agricultural Marketing Service.

My testimony will focus on certain key provisions in S. 1074 which the Department feels could cause dietary hardships and economic burdens for our consumers through the denial of the beneficial use of pesticide tools and lost productivity to our Nation's producers. We believe the impacts which would result from S. 1074 outweigh any potential health benefits from the legislation.

The U.S. food supply is the safest, most abundant, and most affordable anywhere in the world. The judicious application of pesticides plays an important role in providing this food supply. We fully recognize the importance of continuing to strive to do an even better, more effective job of evaluating potential risks from pesticides, and reducing those risks. The Administration shares your goals to ensure public health and environmental protection and to maintain and enhance public confidence in the safety of the food supply. This means we must make regulatory decisions based on the best state-of-the-art science we can bring to bear, through a process and within a time frame that respects the interests and the expectations of all concerned parties, including consumers and farmers.

The Food Safety Plan announced by the President 2 years ago is a comprehensive package of reforms that, taken together, will mark a major step forward in public health and environmental protection. Enactment of the plan will allow EPA to act more promptly and effectively, based on sound science, to deal with problem chemicals and establish a credible system of pesticide regulation.

The President's plan called for:

1. Establishing "negligible risk" tolerance levels which would be applicable to raw commodities as well as processed foods, moving away from the "zero" risk standard of the Delaney clause;

2. Establishing prospectively national uniform pesticide tolerance standards to maximize the efficiency and effectiveness of our domestic and global markets;

3. Requiring periodic review of pesticide registrations to ensure pesticides continue to meet contemporary standards for health and safety;

4. Improving EPA's flexibility in exercising its suspension authority;

5. Revising the cancellation process, replacing the adjudicatory hearing with notice-and-comment procedures;

6. Enhancing the enforcement provisions of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), providing for improved authorities and increased penalties for violations; and

7. Providing for early and appropriate coordination and consultation among Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA) and Health and Human Services (HHS) in the pesticide cancellation and suspension process.

KEY PROVISIONS

Single Pesticide Tolerance Standard. USDA supports legislation that would amend the Federal Food, Drug and Cosmetic Act (FFDCA) to make the same safety standard applicable to pesticide residues in both raw agricultural commodities and processed food.

Under current law, there are two different legal standards for pesticide residues in food. Tolerances for pesticide residues in raw agricultural commodities are subject to risk/benefit determinations under Section 408 of FFDCA. Tolerances for pesticide residues that concentrate in, or are applied to, processed food are issued under Section 409 of the FFDCA, which contains the Delaney clause which if literally interpreted would mean a "zero risk" standard.

In 1987, the National Academy of Sciences (HAS) recommended that pesticide residues in raw and processed food should be regulated on the basis of consistent standards and that a negligible risk standard should apply to all pesticide residues in food. Consistent with the HAS recommendations, this Administration supports elimination of application of the Section 409 "Delaney Clause" to pesticide residues in processed food and supports a uniform negligible risk standard for all pesticide residues in food.

Negligible Risk Standard. USDA supports a negligible risk standard that would require EPA to set pesticide tolerances at a level adequate to protect the public health and the environment.

We support legislation that would implement the NAS recommendation for a uniform negligible risk standard for pesticide residues in food and, in addition, clearly establish a risk/benefit standard. This would give EPA explicit statutory authority to ignore de minimis or insignificant dietary risks and permit the Agency to focus attention on the highest risk pesticides.

The definition of "negligible risk" should not identify a specific level of risk that would be considered negligible or a numerical expression of that level. Because science and the degree of knowledge and confidence in risk assessment is constantly evolving and improving, it is important to preserve EPA's ability to keep pace with the evolving science of risk assessment.

Contrary to the requirements in S. 1074, EPA should continue to have the flexibility to calculate dietary exposure on the basis of the (1) percent of raw agricultural commodities or processed food actually treated with a pesticide, and (2) other data to more closely approximate actual exposure, including information on actual residue levels detected in the treated commodities and the processed food produced from those commodities. This would help avoid unrealistic exposure assessments and would assist in developing more accurate risk projections.

Consideration of Pesticide Benefits. It should be made clear that EPA may establish a tolerance for a pesticide residue posing greater than a negligible risk if EPA determines that the tolerance is protective of public health, and the risk is reasonable in light of both risks, societal benefits, and that reasonable efforts are made to develop alternatives.

This would assure, as is the case for most tolerance determinations, that pesticide tolerance decisions are not made in isolation, and that EPA may fully consider all relevant factors. In this manner, EPA will be able to set reasonable priorities and use its resources to regulate the pesticides with unacceptable risks.

USDA provides information to EPA on the necessity of the use of the chemical for the production of an adequate, wholesome and economical food supply. EPA then considers this information in making tolerance decisions for pesticide residues on raw agricultural commodities. The President's plan would extend that authority to tolerance decisions for pesticide residues on processed food. EPA is currently precluded from taking into account the benefits of pesticides that are applied to or that concentrate in processed food.

Pesticides provide important societal benefits to consumers and producers, e.g., health, nutritional, economic. The loss of important food use pesticides can result in heightened risk of disease causing organisms in food, food price increases, adverse effects on food quality and reduction in the availability of nutritional food choices.

The impact on consumers and their diet can cause particular hardship on the low income sector of our society. In view of the broad range of benefits of food use pesticides, it is important that EPA balance benefits against risks in all pesticide tolerance decisions.

Pesticide Data Program. USDA's Pesticide Data Program (PDP) will improve upon the quality and quantity of food safety information that exists by gathering more information on actual pesticide residue levels in foods. The actual residue data will be provided to EPA for use in conducting risk analysis and in setting pesticide tolerances.

The PDP will use statistically-based product sampling to permit inferences to be made about the larger "population" of products. The sampling process is crucial to obtaining an objective "picture" of pesticide residues and other toxic substances in food.

The pesticide use data collected by the National Agricultural Statistics Service (NASS) compliments the data on pesticide residues collected by USDA's Agricultural Marketing Service (AMS). The NASS data will also assist in identifying pesticide commodity pairs for residue sampling and in devising risk reducing strategies for pest control produced by the Economic Research Service.

National Tolerance Uniformity. Under current law, States may set tolerances for pesticide residues in foods that are lower than those established by EPA. In recent years, a number of States have set lower tolerances for certain pesticides (including EBDC and Alar), creating significant burdens on interstate commerce. We support legislation that sets national uniformity of tolerances for pesticides registered or reregistered under the comprehensive safety data requirements adopted by EPA in 1985. This uniformity would avoid the consumer confusion and substantial burdens on interstate commerce caused by special tolerance requirements set by States and political subdivisions that may not be warranted by any public health or food safety consideration. Consumer protection would be assured by limiting required uniformity to pesticide tolerances supported by current and complete scientific testing and recent EPA approval.

We support a mechanism for States to petition the EPA for an exemption from a uniform Federal tolerance where the State could establish adequate justification. Exemptions should be authorized where EPA has concluded that a special State tolerance is justified by compelling local conditions, such as unusual food consumption patterns.

Pass-through Provision. It is important that food safety legislation retain the provision of current law that if a tolerance or exemption is in effect for a pesticide chemical in a raw agricultural commodity, a residue of that chemical in a processed food made from the raw agricultural commodity shall not be considered unsafe as long as the concentration of the residue in the processed food is not greater than the tolerance prescribed for the agricultural commodity. This provision avoids the necessity of establishing separate tolerances for pesticide residues in processed food and provides recognition of the fact that the majority of pesticide residues do not concentrate in processed food. Where residues are found to concentrate or break down into harmful metabolites, EPA should set tolerances for the processed food on the same basis as on the raw commodities.

The Administration will work with Congress to develop sound legislative language to deal with these issues.

S. 1074 would eliminate the current system of balancing the benefits of pesticides against the risks they pose to society. It would establish an unnecessarily prescriptive method of calculating aggregate negligible risks based on total food uses of a pesticide and on total risks from all pesticides used on a specific crop. The effect would be fewer pesticides available to producers, decreased production, and lower farm income and higher consumer prices. The bill also poses significant risks to the continued viability of U.S. agriculture and threatens to increase the costs to consumers. Pesticide residues generally do not exceed tolerance levels according to the Food and Drug Administration and the National Research Council.

Problems with Pesticides for Minor Use Crops. While the legislation attempts to improve food safety, its value to consumers would be minimal. It could lead to additional burdens by eliminating a wide spectrum of essential crop protection products for many minor use crops and threaten the continued availability of those crops. This will be especially true for consumers of "minor crops," such as most fruits and vegetables, and for producers who rely upon pesticides for which there is a limited market.

This situation is the result of a process by which EPA must reevaluate all existing agricultural pesticides. Amendments passed by Congress in 1988 to the Federal Insecticide, Fungicide, and Rodenticide Act set a series of deadlines for completing the

reregistration process. Those amendments not only placed significant new requirements on EPA but required registrants to pay a significant portion of the reregistration costs.

The legislation in S. 1074 could compound the difficulty faced in reregistration efforts for minor use pesticides by requiring extensive new data on food consumption which could be difficult to obtain for food not widely consumed. In addition, the new restrictive negligible risk standards and exposure assumptions could force the cancellation of uses without significant actual risks.

As a result, many registrants will respond to the increased cost of testing and tight deadlines by reducing the number of pesticide uses they support for reregistration. Under the provisions of reregistration, registrants have the option of deleting pesticide uses by voluntarily withdrawing registration of product uses that are not economically desirable to maintain. In those cases, EPA has the responsibility to cancel the registration for crop use.

Pesticide registrations already have been canceled for numerous fruit and vegetable crop uses. Often these cancellations are due to the cost of data requirements rather than risk concerns. Many more uses are expected to be dropped in the near future. USDA and EPA have recognized that much needs to be done if agricultural producers are to deal successfully with the consequences of reregistration. We are working aggressively with the chemical companies and producer groups to deal with current and anticipated problems so that we may better identify and meet the needs of minor use chemical customers.

CONCLUSION

While the department opposes the prescriptive standards of S. 1074, we agree that the Federal laws for food safety and pesticide use need to be revamped in a manner that will not severely impair new scientific and technological breakthroughs in the agricultural chemical industry. It is imperative that we proceed in a responsible manner so as not to jeopardize this Nation's agricultural industry which represents some 20 percent of our GNP. We urge the committee in its deliberations to consider the adverse impacts of S. 1074 on American agriculture and the consuming public.

Mr. Chairman, this concludes my statement. I will be glad to respond to any questions the committee may have.

The CHAIRMAN [presiding.] Thank you very much. I apologize for my brief absence.

Let me ask you, Ms. Fisher, why is it inappropriate to have a children's standard in the legislation?

Ms. FISHER. Senator, we believe that there should be additional protections for children, and under our current system we do take into account the fact that children eat more and eat more of certain foods per pound of body weight than adults do. So we think our current process does take into account the fact that their eating habits are not the same.

We have asked the National Academy of Sciences to advise us on whether or not the process we use, even with those additional protections, is adequate enough—in other words, are we doing enough to protect children—and I think based on the information we get from that study we may be able to better assess both as an agency and you as the legislative branch what additional protections need to be taken.

Our concern with the standard in your bill is that we are not sure of the scientific underpinning for it, and we're not sure whether or not it is in fact the right way to go or necessary.

The CHAIRMAN. Well, what exactly is your standard for the protection of children?

Ms. FISHER. Well, what we take into account——

The CHAIRMAN. Well, "take into account" are rather general words. We all take into account various considerations. I am inter-

ested specifically in what are the processes, procedures, the tests that are followed with regard to children.

Ms. FISHER. OK. I'll even use any one of the charts up there. When we do our mathematical calculations to determine what the exposure is of children, we look at their consumption factors, which I think Dr. Wargo shows as much higher in the first few years. He has broken it down into individual years. We have age grouping of infants, children one to 6, so we are not quite as precise as he is. But in our mathematical calculation we do take into account the higher consumption factors that he has shown on his charts there for categories of ages, not individual years.

We have used categories because as he correctly pointed out, that's what we have the data for. We do not have very precise data to look at consumption on a year by year basis as he has laid out.

The CHAIRMAN. Is your database the same one that he referred to as going back to the 1970's?

Ms. FISHER. That's correct.

The CHAIRMAN. Has there been any attempt to upgrade it?

Ms. FISHER. There was an attempt. USDA did try to update it in the late 1980's. There was a survey that was done I believe in 1987 and 1988, but it has some significant flaws with it, and we have worked with USDA to try to come up with improvements to surveys over the next couple years. So we are in the process of trying to improve our database, but there are definitely flaws in the most recent data.

The CHAIRMAN. Could you tell us how many tolerances are currently in existence that have been established or revised specifically on the basis of data on children's exposures?

Ms. FISHER. Senator, I don't have a number right offhand that I can give you that shows numbers of tolerances that have been revised lately. When we do review a pesticide and take a regulatory action on it——

The CHAIRMAN. Well how many—are we talking about a dozen, or 100——

Ms. FISHER. There are thousands of tolerances on the book. All of those will be revised as we review each of the chemicals under our FIFRA 1988 procedure.

The CHAIRMAN. My specific question is what has been revised on the basis of data on children's exposures. You have indicated you consider the unique sensitivities of children, and I think there is a fair point to be raised about micromanagement and over-regulation by establishing precise formulas and mathematical formulas, and you have indicated that you think it can be much better done by just taking into consideration some of these matters and demonstrating sensitivity to them. I'm just asking you if you could tell us about any tolerances that are currently in existence that have been established or revised specifically on the basis of children's exposures.

Ms. FISHER. Our computer system that takes this kind of information into account is relatively new; I think it has only been up and running for the past couple years, so the number is rather small. I would have to provide for the record what the exact count is.

The CHAIRMAN. All right. Couldn't many of your concerns about the collection of data in children be resolved by having registrants collect information which EPA could analyze?

Ms. FISHER. Yes. They could provide more information in terms of the toxic effect. We have started to ask for more information on the neurological problems caused by individual pesticides. Currently the registrants do not give us consumption data, which might be the issue that you are talking about. We rely on the USDA for the consumption data.

The CHAIRMAN. Mr. Haley, from your own perspective, do you think it is inappropriate to have a children's standard in the legislation?

Mr. HALEY. I think we are all awaiting the NAS report which would point out the problems with children.

The CHAIRMAN. Are you prepared to support it if NAS recommends it?

Mr. HALEY. If it is reasonable, no doubt in my mind we are willing to adopt it. Mr. Chairman, I think this administration is as concerned about children, and if children are more at risk in the food supply, they deserve more protection. I don't think anyone is going to deny that. I think the question comes at what level and to what degree.

The CHAIRMAN. Given what you know about the increasing risk for children, you are still going to leave it up to the Academy of Sciences, and you are not prepared yourself, understanding what you do understand in terms of the health needs of children, to make any specific additional recommendations for their protection.

Mr. HALEY. We are working as we speak with EPA to develop food consumption surveys that would incorporate subpopulations including children, the elderly and others. So we are working on that right now.

The CHAIRMAN. But you are not prepared to mention any of them today.

Mr. HALEY. We do not have the results of those studies to make those recommendations today.

The CHAIRMAN. And what studies are these?

Mr. HALEY. These are the food consumption surveys where we actually look at food consumption around the country, and we are in the process of——

The CHAIRMAN. Are you doing it specifically with regard to children?

Mr. HALEY. I believe we are working directly right now on subpopulations including children.

The CHAIRMAN. Do you have examples of those surveys that you could submit now for the record?

Mr. HALEY. We do have some surveys that we could submit for the record that we have done, food consumption surveys.

The CHAIRMAN. Do you have them here with you?

Mr. HALEY. No, we do not have them here.

The CHAIRMAN. Are these the 1987-'88 surveys?

Mr. HALEY. That's correct.

The CHAIRMAN. But you don't have anything following that. Are you familiar with the GAO's evaluation of those studies?

Mr. HALEY. I am, Senator.

The CHAIRMAN. What was it?

Mr. HALEY. They were critical of it and for a very good reason. I think the GAO study points out that the study as a whole for the general population was an accurate one, or one that we could rely on. What they did is they said the response rate to the subpopulations we used was inappropriate and not enough. We agree with that, and that is the basis of my statement that we are currently working with EPA to remedy that situation and deal with the recommendations of the GAO report.

The CHAIRMAN. What I am hearing from you is that you don't like our program, that you are doing some additional reviews and surveys, that they are basically the 1987 and 1988 surveys which have been discounted by GAO, and that you are doing additional studies as to how to reach the children's group—combined with the statement that this administration is as interested as anybody else in the problems of children. Well, I'll let the record stand on that unless you want to give me an additional response, because that I think is a pretty weak one.

Do you understand why we are troubled?

Mr. HALEY. I understand your point. Can we do better? The answer is yes, we are in the process of doing just that.

The CHAIRMAN. No, I'm not satisfied with your point that we can always do better. We can't always do better. What we're talking about is a very special, identifiable, vulnerable group in our society that have very special vulnerabilities in terms of tolerance levels, and what the USDA is doing about it.

Mr. Shank, the FDA supports the bill's adoption of a negligible risk standard but argues that the one in one million or any specific standard is too restrictive and that there will always be a significant possibility for better science in the future. But shouldn't we adopt a clear standard now that will restore confidence in how pesticides are regulated?

Mr. Shank. Mr. Chairman, yes, I think we should. And I don't want to suggest that one in one million might not be an appropriate standard. In the vast majority of cases, I think the one in one million would be. But the prescriptive nature in which the risk assessment is mandated within the bill is what we find most troublesome. It is a very conservative assessment that would probably result in a standard that is much more severe than one in one million as we currently know it.

The CHAIRMAN. Have you formed any position with regard to the need for a children's standard for pesticide exposure?

Mr. SHANK. The Food and Drug Administration is looking forward to the receipt of the National Academy of Science report. We will consider the recommendations contained therein because we too are concerned that we provide the appropriate standards for the children of our Nation.

The CHAIRMAN. It is interesting that we can't make some judgments about these matters. I think the Academy of Sciences, by and large and in a wide range of different areas, has given us enormously valuable and helpful information, but as we have heard, many of those who are on that panel, who have spent most of their professional lifetimes in these areas, have demonstrated the importance of developing that standard.

You are familiar with the 1986 GAO study that documented that the routine, analytical method of FDA's monitoring program could not monitor over 40 percent of the pesticide residues in food. Does the FDA now have the capacity to routinely analyze all the chemicals likely to become residue on food?

Mr. SHANK. Mr. Chairman, we are completely familiar with that report. FDA does have the analytical capabilities to analyze for all pesticide residues. The point that is being made is that with the large volume of different chemicals and commodity combinations, the multiresidue methods that we routinely rely upon account for somewhere between 40-50 percent on a routine basis. But we can go to the other commodity-pesticide combinations which we routinely do if we have a reason to suspect or have a need to do so.

The CHAIRMAN. So you "routinely" do that?

Mr. SHANK. That may have been a poor choice of words—which we often do whenever we have a reason to look at that particular pesticide residue.

The CHAIRMAN. How frequently?

Mr. SHANK. Senator, the basis of our program is the multiresidue methods which cover approximately 50 percent of the tolerances that have been established.

The CHAIRMAN. Ms. Fisher, let me ask, what is the administration's plan for moving on food safety this year? Do they have any?

Ms. FISHER. Yes, Senator. As you know, the President has supported amending both FIFRA and FFDCA, focusing particularly on seven points. We are working within the administration and hopefully shortly, sometime this summer, we will have clarified our positions and get them up to you.

The CHAIRMAN. Fine.

Senator Simon.

Senator SIMON. May I take advantage of your presence to ask you about something that is not included at the present time in the proposal? May I ask you about the whole question of imports and what we do in this area.

What percentage of the fruits and vegetables that we consume are imported? Do any of you know?

Mr. HALEY. About one-third.

Senator SIMON. About one-third. Any comments from any of you on the safety of the fruits and vegetables we consume that are imported?

Mr. HALEY. Senator, through our monitoring program—and I would suggest that we probably don't look at as many samples as we'd like—but we find very comparable rates as far as those residues that are on produce or on product that would violate the tolerance. We're talking in the range of one to 4 percent of those that we look at that we have problems with domestic imports. It is slightly higher for imported, but in the same ball park.

Senator SIMON. When you say you don't do as much as you would like, do you do enough so that you feel confident in telling me that it's slightly higher but not significantly higher than what is accurate?

Mr. SHANK. The confidence that we have comes from the history and the data that we have accumulated. Year after year, we see similar results. The data that the States provide to the system,

which is more than what FDA generates themselves, their results are consistent with ours. It is through that manner of the accumulation of evidence, if you would, that we feel comfortable, not necessarily what we do any 1 year.

Senator SIMON. And do you feel a similar comfort with meats that are imported?

Mr. HALEY. Senator, let me see if I can answer your question. When I was with the State of California no more than 2 years ago, we did a lot of food inspection, 16,000 samples, and we did a lot of imports. And I think to corroborate what Mr. Shank has said, we found very similar results. Approximately 85 percent of the food coming in had no residues; 13 to 14 percent had residues under 50 percent of the tolerances, and we had some violation rates of one or 2 percent. It doesn't mean that those problems were health violations; they were because of drift or other things.

That is FDA's findings; it is the State of California's general findings; it is the State of Florida's general findings, Texas, Michigan and New York. You'd think somewhere around the country we would have a blip in it, but it is an actual picture of our food supply.

Senator SIMON. And are you talking about fruits and vegetables only?

Mr. HALEY. Fruits and vegetables. In regard to meat, we have a system at USDA that requires and "equal to" inspection system that we verify for those meats coming into the country, so we have some confidence that the meat coming in here is as safe as the domestic supply.

Senator SIMON. A former director of the FDA told me that in terms of meat supply, there just weren't have adequate protections in terms of inspections. That is not accurate?

Mr. HALEY. I am not saying that that does not happen on occasion, and while we go around and monitor these inspection facilities, we have that inspection here coming into the country. So our meat inspectors are involved in that process.

Senator SIMON. Mr. Shank, do you wish to comment?

Mr. SHANK. Yes, Senator. I yielded the floor to USDA because they are responsible for the meat products, and I don't take exception with what he said.

Senator SIMON. Let me ask all three of you: what about the ability to send pesticides to other countries that are prohibited in this country?

Ms. FISHER. Under current law EPA does not have the authority to prohibit the export of a pesticide that we have banned here. The administration has supported an amendment to FIFRA that would give us that authority. But today it is legal—if I ban a pesticide in America because of its health risks, manufacturers can still produce it here and sell it overseas.

Senator SIMON. And you would support a change in the law in that regard?

Ms. FISHER. Yes. We have supported changing FIFRA to allow us to ban the export of a pesticide that we have banned for use in America.

Senator SIMON. What about not only permitting you to do it, but requiring you to do it?

Ms. FISHER. The same, yes.

Senator SIMON. OK. Any comments from Mr. Shank or Mr. Haley on that? [Pause.] I gather you concur with Ms. Fisher by your silence.

Mr. SHANK. Yes, I support the fact that additional controls in these areas would be beneficial. However, I would hasten to point out that through our monitoring data and the data we have available to us, this so-called "circle of poison" does not demonstrate itself in the data.

The residues for those persistent pesticides that remain behind are very low, and we have not seen any evidence of potential public health concern.

Senator SIMON. But is it not a fact that there are areas in other countries where they use pesticides for products locally consumed, but do not export these products to the United States because they know they would have problems here? Aren't we in fact endangering citizens in those other countries?

Mr. HALEY. I think it is important to note that the administration position agrees substantially with the language of that bill that prohibits the export of "bad actors", those that are environmentally and toxicologically of significance. So we support that concept. What we don't support is the prohibition of pesticides that are used in a different country for a variety of other reasons—climatic, soil types and the like—that have OECD registration, as Linda said, have analytical methods, have a prior informed consent law, and that information is available to us.

We still maintain that any of those products that are not registered in this country cannot come into this country, but we do not dictate our system on other areas of the world.

Senator SIMON. I understand.

I thank you. I think this is an area where, frankly, we do need some action, and I hope we can get it.

Thank you, Mr. Chairman.

The CHAIRMAN. I would agree with Senator Simon. The complex reality is that a lot of these companies, when we do ban certain pesticide use, go overseas and produce it and ship it. That's what we've seen with the pharmaceutical companies over a period of 25 or 30 years. So it is a difficult and challenging issue, and I'm basically in strong support of the points that Senator Simon has made.

I want to thank all of you very much for your responsiveness and your help.

On the third panel we'll hear from Janet Hathaway, Natural Resources Defense Council; Enrique Guardia, representing the National Food Processors Association; Sherwin Gardner from Grocery Manufacturers of America, and Jay Vroom, president of the National Agricultural Chemical Association.

We'll start with Ms. Hathaway. If you'd be good enough to summarize your testimony, we'd be very grateful for that.

Ms. HATHAWAY. I'd be happy to do that, Mr. Chairman.

The CHAIRMAN. We appreciate very much your presence, and we'll include all the statements in their entirety in the record.

STATEMENTS OF JANET HATHAWAY, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, WASHINGTON, DC; ENRIQUE J. GUARDIA, SENIOR VICE PRESIDENT OF SCIENTIFIC RELATIONS, KRAFT GENERAL FOODS, ON BEHALF OF NATIONAL FOOD PROCESSORS ASSOCIATION, WASHINGTON, DC, ACCOMPANIED BY CLAUSEN ELY, COUNSEL; SHERWIN GARDNER, SENIOR VICE PRESIDENT, SCIENCE AND TECHNOLOGY, GROCERY MANUFACTURERS OF AMERICA, WASHINGTON, DC; AND JAY VROOM, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, WASHINGTON, DC

Ms. HATHAWAY. Mr. Chairman, I appreciate the opportunity to testify before this committee about the risks that children face from pesticides in food.

Two years ago, NRDC conducted a study that has been the subject of some debate, and I want to take a moment to address that before we get into some of the details of your legislation.

Just yesterday, there was an unfortunately very misleading and in some ways very mistaken New York Times front page article about alar, implying that there was really no risk from alar and that there had been hysteria in the public that was produced, I guess, the implication was intentionally by the Natural Resources Defense Council.

That's just flatly wrong. The study that we conducted was a very deliberative two-year effort to identify the actual residue levels, the actual consumption patterns, and the real risks that children face from pesticides in food. Of the 23 pesticides we looked at, the risk was much, much higher from alar, and as a consequence that was the subject of a lot of public attention and media attention.

But let me just go over a couple of the basic assumptions so people understand there was no way in which that was a worst case analysis. It was a real world analysis. And in fact Dr. Jackson just handed me an article that California Department of Health Services just published, saying that the NRDC study was not a worst case analysis and that indeed the California Department of Health Services believes that the risk from alar may be even higher than we estimate it.

First, the risk that we looked at was only the risk from UDMH, the breakdown product. Alar itself may or may not be a carcinogen. We didn't assume it to be a carcinogen. We just looked at the risk from the breakdown product which occurs especially in the processing of apple products.

Second, we looked at not the legal limit, not the actual tolerance level of the pesticide in food, but the residues that Uniroyal, the manufacturer itself, said were in the food in 1986. They conducted a study at the request of EPA.

Third, we looked at actual consumption. People have suggested that thousands of pounds would have to be consumed of this product. Not so. The average consumption of a child under age 6 is three ounces of apple products. You probably know many children certainly consume more than that. But we looked at that, and that was the average, and we used that data in constructing the kind of risk that was involved.

And fourth and I think most importantly, our number does not significantly differ from EPA's conclusion about alar and UDMH. EPA said that the risk for the average adult was essentially 50 times the acceptable level, the one in one million level. NRDC said that the risk for children under age 6 was 250 times the one in one million level. Both EPA and we agree that kids' risk is much higher; EPA never put a number on what they thought that kids' risk would be.

So that's where it stands, and I do think that alar is important to remember because it is a real world case of what happens when we don't have an adequate and responsive regulatory program that in advance averts these kinds of food chemicals from being in the production process.

Alar is one instance of it. Aldicarb is another. Aldicarb was removed from the market. I think it was commendable that it was done by a voluntary cancellation by the companies. But it should never have been allowed to be used at those levels. And I think that that is a very important point to be made. There were thousands of poisonings in California as Dr. Jackson said. It is not appropriate to use a chemical like that without having substantial margins of safety.

That's what this bill does. Let's turn to this bill, and I really want to ask the other panelists to answer why are they afraid of this bill. If the food supply really is safe, as they have been saying, if one in one million is routinely met by the food that is in our grocery stores, on our plates when we have dinner, what are they afraid of in this bill? This bill simply says systematically go through the pesticides that are on the market; make sure that the residue levels that are legal are safe; make sure that they are safe not just for the average adult but for children and other people who are heavier consumers of the food. That's just common sense.

If the food supply is safe, nothing is going to change. If some of these tolerance levels are unsafe, the tolerance levels are going to have to be revised. I submit that there are tolerance levels that will have to be revised. I can't tell you how many. I don't think it is the majority of foods that will have to have those revisions, but I think it is some, especially in the fruit and vegetable commodities, the pesticides used on those foods.

Let's admit that there is a real dysfunction between protecting kids from pesticides in food and what we have been doing in the past. In the past we have been looking at average adult exposures. In the past we have been looking at commonplace agricultural practices and not at the real residues that remain. We have not looked at the concentrations that occur in kids' diets because of their lack of diversity in what they consume, and we've got to do that, and let's just get with the task. That is what this bill says. I think it is so common sensical that I am surprised that we continue to debate it.

EPA says that one in one million is the standard they use. Yesterday's New York Times said erroneously that if a chemical poses more than a one in one million risk, EPA is required by law to ban it.

I wish that were so. That's not so. This bill would require that the tolerance levels be such that no one would be experiencing

more than one case of cancer out of a million people exposed kind of risk. That is prudent. That is a step that goes very far in the right direction. And I applaud the chairman and other members who have supported that legislation.

Thank you.

[The prepared statement of Ms. Hathaway follows:]

Prepared Statement of Ms. Hathaway

Thank you for the opportunity to testify before this committee about S. 1074, the Safety of Pesticides in Food Act of 1991. I am Janet Hathaway, a senior attorney with the Natural Resources Defense Council (NRDC), a national, nonprofit environmental organization dedicated to protecting public health and the environment. This testimony is also submitted on behalf of my colleagues, Al Meyerhoff and Lawrie Mott, who have devoted over a decade to improving the safety of the food supply and the environment, particularly with regard to reforming the use of agricultural chemicals. Al Meyerhoff is a senior attorney and Lawrie Mott is a senior scientist with NRDC's San Francisco office.

During the last decade, NRDC has issued a series of reports documenting the hazards of pesticides in the food supply. In 1989, we released Intolerable Risk: Pesticides in Our Children's Food which documents that the risks from actual residue levels of 23 pesticides used in 27 fruits and vegetables greatly exceed even the government's own standards for acceptable risk.[1] Earlier NRDC reports described the unique pesticide risks associated with imported food,[2] the extent of pesticide contamination of fruits and vegetables,[3] and the inadequate government regulation of pesticides on food.[4]

We have testified many times before the Senate Labor Committee and other Congressional committees concerning the need to reform federal pesticide laws. We are here today to support

---

1. Sewall, B., R. Whyatt, and J. Hathaway, Intolerable Risk: Pesticides in Our Children's Food, 1989.

2. Hearne, S., Harvest of Unknowns: Pesticide Contamination in Imported Foods, 1984.

3. Mott, L. and K. Snyder, Pesticide Alert, 1987.

4. Mott, L. and M. Broad, Pesticides in Food: What The Public Needs To Know, 1984.

S. 1074 as a positive step on the long road ahead to protect the public from the hazards of pesticides. By establishing purely health-based standards for pesticides in food, this legislation will substantially improve the safety of our food supply. This legislation should be strongly and rapidly endorsed by the Congress and signed by the President. Changes are needed not just in the law but also in practices used to grow our food at farms and orchards across the country and throughout the world. In the long term, public health and the environment will be best protected by phasing out the use of known hazardous pesticides with the use of safer alternative pest control methods.

I.

PESTICIDES IN FOOD:
THE SLOW POISONING OF THE AMERICAN PUBLIC

Five years ago, the Director of EPA's Pesticide Program during the Reagan administration said, "Pesticides dwarf the other environmental risks the Agency deals with. Toxic waste dumps may affect a few thousand people who live around them. But virtually everyone is exposed to pesticides."[5]

Recently, Administrator Reilly echoed these remarks, stating:

> "The [EPA] Science Advisory Board identified pesticides among the top priority concerns, both as they affect applicators and also the consumer of food containing pesticide residues. I propose now that we make food safety a top environmental legislative priority in the new Congress.... President Bush and I both understand and share the public's frustration. We know national pesticide laws are arcane and antiquated."[6]

5. Shabecoff, P., "Pesticide Control Finally Tops the EPA's List of Most Pressing Problems," New York Times, March 6, 1986.

6. Address by William K. Reilly, Administrator, United States Environmental Protection Agency, to the Commonwealth Club, San Francisco, CA, January 9, 1991.

But action has not matched rhetoric. Pesticides continue to be routinely allowed in the nation's food supply with woefully inadequate regulation or even detection. According to the state and federal pesticide monitoring data for the years 1982 to 1985, a total of 110 separate pesticides were detected in 48 percent of the samples tested. Many of these substances have been linked to cancer, nerve damage, genetic mutations and other adverse health effects. However, the full extent of pesticide contamination of the food supply is unknown, primarily because the government's routinely-used residue monitoring techniques do not detect many pesticides applied to food. The Congressional Office of Technology Assessment found that the U.S. Food and Drug Administration's (FDA) primary laboratory method can detect only about half the pesticides registered for use on food. For the rest, we are regulating -- or not regulating -- out of ignorance.

At least 63 of approximately 300 pesticides used on food have been classified by EPA as "probable" or "possible" human carcinogens. The cumulative risk to the public health, especially the health of children, from this daily dose of toxic chemicals is unknown. However, disturbing new data indicate an increasing incidence of cancer generally.

One out of nine American women will now contract breast cancer during their lifetime, a more than one-third increase in just this decade. Among children fourteen and younger, the incidence of cancer in the United States has increased 21.5 percent from 1950-1986, according to the National Cancer Institute. Other forms of cancer also are on the rise. Even adjusted to account for increases caused by an aging population, there have been sharp increases in: brain cancer (up 22.3 percent), bladder cancer (up 49.2 percent), testicular cancer (up 92 percent), skin cancer (up 263 percent), kidney cancer (up 95 percent) and non-Hodgkins lymphoma (up 130 percent). All new cancer cases combined have risen by 37 percent. New cancer cases, excluding lung cancer, have risen 27 percent. More than one million Americans will learn they have cancer

this year; half a million will die from it.[7] How much of this cancer, and the human suffering it engenders, resulted from pesticides? While EPA has tried to quantify it at six thousand cancers per year, no one really knows. Prudence and common sense dictate that a sound public policy should result in reduction or prevention of exposure to substances known to cause cancer, especially children's exposures.

Regrettably, EPA continues to stress "management" of risk from cancer and other pernicious diseases rather than prevention. As a result of the 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) requiring comprehensive testing of pesticides, more and more pesticides found in processed foods are now being determined to cause tumors. They have not been eliminated from our food supply even decades after their cancer-causing potential was revealed. Yet in enacting the Delaney Clause of the Federal Food, Drug and Cosmetic Act Congress expressly and unequivocally prohibited such residues. Rather than comply with the law, the Agency has simply chosen to "amend" it by administrative fiat, both intruding upon the power of Congress and failing to protect the public health as well. The Agency's failure is now being tested in the courts.[8] As a result, nationwide injunctive relief, rather than thoughtful regulatory action, may soon be brought to bear on numerous carcinogenic pesticides now being discovered in food.

---

7. National Cancer Institute, 1989, American Cancer Society, 1986. "Cancer Facts and Figures," as cited in Dr. Devra Lee Davis, "Natural Anti-carcinogens: Can Diet Protect Against Cancer?" Healthy & Environment Digest, February 1990.

8. People of State of California, et al. v. William K. Reilly, et al., No. S-89-0752-RAR-EM (E.D. Cal. May 25, 1989).

Kathleen E. Less, Petitioner, et al. v. William K. Reilly, et al., Respondent No. 91-70234 (9th Circuit, April 12, 1991).

II.

POLLUTION PREVENTION:
REDUCING THE USE OF PESTICIDES

> The question of chemical residues on the food we eat is a hotly debated issue. The existence of such residues is either played down by the industry as unimportant or is flatly denied. Simultaneously, there is a strong tendency to brand as fanatics or cultists all who are so perverse as to demand that there food be free of insect poisons. In all this cloud of controversy, what are the actual facts? [...]
>
> The system by which the Food and Drug Administration establishes maximum permissible limits of contamination, called "tolerances," has obvious defects. Under the conditions prevailing that provides merely paper security and promotes a completely unjustified impression that safe limits have been established and are being adhered to. As to the safety of allowing sprinkling of poisons on our foods -- a little on this, a little on that -- many people contend, with highly persuasive reasons, that no poison is safe or desirable on food. [...] In effect, to establish tolerances is to authorize contamination of public food supplies with poisonous chemicals in order that the farmer and the processor may enjoy the benefit of cheaper production -- then to penalize the consumer by taxing him to maintain a policing agency to make certain that he shall not get a lethal dose. But to do the policing job properly would cost money beyond any legislator's courage to appropriate, given the present volume and toxicity of agricultural chemicals. So in the end, the luckless consumer pays his taxes but gets his poisons regardless. [...]
>
> This system, however -- deliberately poisoning our food, then policing the result -- is too reminiscent of Lewis Carroll's white knight who thought of "'a plan to die one's whiskers green, and always use so large a fan that they could not be seen.'" The ultimate answer is to use less toxic chemicals so that the public hazard from their misuse is greatly reduced. [...] In addition to making this change to less dangerous agricultural pesticides, we should diligently explore the possibilities of non-chemical methods. A great many other possibilities exist for effective insect control by methods that will leave no residues on foods. Until a large-scale conversion to these methods has been made, we shall have little relief from a situation that, by any common sense standards, is intolerable. As matters stand now, we are in little better position than the guests of the Borgias.[9]

For three decades since Rachel Carson wrote these stirring words, calls for essential reform of the nation's food safety laws have gone largely unheeded. When governmental agencies or private groups have demonstrated that pesticide regulation is necessary in order to protect public

9. Rachel Carson, Silent Spring, 1962, pp.182-184.

health, a "parade of horribles" has been conjured up by the food and agrichemical industries opposing government action. Chemical by chemical, we have been told that pesticides were "essential" to food production and that their elimination, despite clear health hazards, would wreck havoc on segments of American agriculture. Chemical by chemical, after excruciatingly long bureaucratic delays and public debate, these claims were proven false. In the early years, these apocalyptic predictions were made for the chlorinated hydrocarbons (e.g., DDT, aldrin and dieldrin). After years of litigation, these substances were finally removed from the marketplace with no noticeable impact on agricultural yields or production. During the Nixon and Carter Administrations, it was DBCP that stirred the greatest controversy. DBCP is a human carcinogen and potent reproductive toxin. DBCP users and manufacturers claimed that removal of DBCP from the market would have a devastating impact on the production of citrus and other commodities. After a decade of controversy, the pesticide was finally banned, first by California and then by EPA. Citrus yields increased. But Americans continue to be exposed to DBCP, which has now contaminated some 2,000 drinking water wells in California alone. A lawsuit brought by the city of Fresno is now pending against DBCP's producers for several hundred million dollars in damages resulting from DBCP pollution of Fresno's drinking water supply. Birth defects and other reproductive harm have already been attributed to DBCP; its long-term cancer impact remains to be seen.

During the Reagan Administration, the spotlight was on ethylene dibromide (EDB), used to replace DBCP and also a potent carcinogen and reproductive toxin. Again Americans were told that EDB was vitally necessary for grain fumigation, as a nematicide used on citrus, and for a variety of other purposes. Again, apocalyptic claims about its proposed removal were made by its producers and by representatives of the food industry. Following years of litigation and a series of scandalous closed-door meetings between high-level EPA officials and the regulated industry, a

major public controversy and action by several individual states combined to convince then Administrator William Ruckelhaus to ban the chemical. Interestingly, grain supply did not dwindle and citrus yields did not diminish. Also during the Reagan Administration, heptachlor, a known carcinogen, was found to contaminate much of the milk in the state of Hawaii. Its use had been permitted on pineapples whose leaves were fed to dairy cows. Before this use was finally banned, 90 percent of Oahu's milk had to be destroyed.

During the Bush Administration, the pattern continues. A few years ago, EPA announced its intention to ban the pesticide dinoseb because of highly disturbing test data in laboratory animals demonstrating that it caused deformities of the fetal brain and spine, male sterility and reproductive harm. Representatives of the agricultural industry, particularly from the Pacific Northwest, utilized their political muscle to prevent dinoseb's removal from the market. Again, we were told that the ban of dinoseb would have dramatic adverse economic impacts on the production of caneberries and other crops for which no alternative pest control method was said to be possible. Years later, EPA eventually prevailed in the courts, and dinoseb was removed from the market. The production of caneberries continues unabated.

Perhaps the most notorious case of false claims of "essentiality" is the now well-known case of the growth regulator Alar. Studies linking Alar and its metabolite UDMH to cancer appeared as early as 1973. The EPA proposed to cancel all food uses of Alar in the fall of 1985, but following a series of private meetings with pesticide industry representatives, its use was allowed to continue. In the spring of 1989, a report issued by the Natural Resources Defense Council documented the health risks posed by Alar and UDMH, especially to infants and young children as a result of children's consumption patterns of apple products at levels ten times or more than that of adults. The Environmental Protection Agency stated that the cancer risks presented by Alar were "unacceptable" and EPA's Administrator "found an inescapable correlation between

exposure to UDMH and life-threatening tumors" in laboratory animals. In response, Alar's manufacturer, the Uniroyal Corporation, claimed that Alar's removal from the market would have devastating effects on apple production, yields and quality. Nevertheless, increasing consumer pressure, as well as the threat by Congress itself to ban the substance, finally convinced its manufacturer to "voluntarily" withdraw Alar from the market worldwide. Contrary to industry's claims, since Alar's removal from use, apple yields, price and quality have not diminished. Indeed, last year's apple harvest was among the highest in the last 20 years.

It is no wonder that public confidence in the food supply has been shaken. It is no wonder that opinion polls consistently show deep-seated public support for reform of the nation's food safety laws. Given this sorry record of crying wolf, claims by industry that purported "benefits" and "essentiality" of known cancer-causing agents must outweigh their health risks should be given short shrift. Rachel Carson was right: "The ultimate answer is to use less toxic chemicals so that the public hazard from their misuse is greatly reduced." In the short term, strict controls should be placed on residues in order to reduce the threat of cancer and other adverse health effects as much as possible. In the long term, given the vagaries of cancer risk assessment and the overall adverse environmental impact of pesticides, including by contaminating drinking water supplies, the workplace, and rural communities, dangerous chemicals should be phased out of use entirely. Alternative, safer pest control methods should be researched, promoted and used more comprehensively in all sectors of agriculture.

In a report describing EPA's accomplishments in the last two years, EPA Administrator William Reilly announced that pollution prevention is the best way to reduce risk. With pesticides, numerous alternative agricultural techniques are already available to reduce the use of these chemicals. Last month, NRDC released Harvest of Hope: The Potential for Alternative

Agriculture to Reduce Pesticide Use.[10] This two-year research project revealed that currently available alternative agricultural methods could reduce pesticide applications between 25 and 80 percent in nine U.S. crops.

The promise of alternative pest control remains unfulfilled. Its implementation, which could be greatly enhanced by enactment of S. 1074, will not only improve the safety of the food supply. It will also reduce the increasing threat agricultural chemicals pose to the nation's public health, groundwater, and environment as a whole.

III.

THE DELANEY CLAUSE IS VITAL TO THE PROTECTION OF OUR FOOD SUPPLY FROM CARCINOGENIC COLOR ADDITIVES, FOOD ADDITIVES AND ANIMAL DRUGS

In addition to the Delaney Clause which pertains to pesticides in processed food, which this bill would modify, there are three other Delaney clauses in the food law which prohibit carcinogenic food additives, color additives and animal drugs. Many food industry representatives, as well as the Food and Drug Administration, have sought to amend or repeal the other three Delaney clauses in the FFDCA.[11] NRDC strongly opposes any such effort. An absolute prohibition on carcinogens is the appropriate standard for regulating food additives, color additives and animal drugs. We would vehemently oppose amendments, even if coupled with improvements to the regulation of pesticides, which undermine the strict Delaney prohibition on those

10. Curtis, J., T. Kuhnle and L. Mott, Harvest of Hope: The Potential for Alternative Agriculture to Reduce Pesticide Use, 1991.

11. In 1988, an FDA official told the House Energy and Commerce Committee, "We believe that this [negligible risk] reasoning reflects good public policy and should also apply to other substances regulated by FDA that are subject to Delaney provisions." Testimony of John M. Taylor, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, before the Health and Environment Subcommittee, House Energy and Commerce Committee, June 23, 1988, p. 4.

carcinogenic substances used as food additives, color additives or animal drugs. Improved safety of the pesticides used in our food supply must not be achieved at the expense of increasing the hazards from other carcinogenic substances in food.

IV.

S. 1074 IS ESSENTIAL
TO IMPROVE THE SAFETY OF OUR FOOD SUPPLY

A. S. 1074 REQUIRES PESTICIDE TOLERANCES TO POSE NO MORE THAN A NEGLIGIBLE RISK, INCLUDING FOR INFANTS AND CHILDREN.

The centerpiece of this bill is the requirement that pesticides used in food must pose no more than a negligible risk, defined as a rate of adverse human health effects of no more than one case in a population of one million exposed people. The bill requires that the EPA must ensure that "identifiable population groups (such as infants and other children)" are not subjected to a higher risk level. NRDC regards this provision as essential to public health protection.

EPA's pesticide risk assessments and the resultant regulatory decisions generally assume an "average" diet. Average consumption estimates, which are derived by dividing the total quantity of a food sold in the United States by the total U.S. population, has very little relevance to the real consumption by individuals. Virtually every individual's diet deviates considerably from that of an average American's. Most individuals concentrate their diets on certain "favorite" foods and avoid other foods altogether. The consequence is that EPA's pesticide tolerances protect the theoretically average consumer -- but not the actual person who eats an apple, or two, a day. EPA's tolerances do not protect consumers from developing cancers or other diseases caused by pesticides remaining on food. S. 1074 would require EPA to ensure that tolerances protect infants, children and other people who eat more than "average" amounts of food treated with pesticides.

1. Explanation of Children's Enhanced Risk

NRDC demonstrated in our Intolerable Risk study that preschoolers have greater exposure to pesticide residues than adults. This is so because preschoolers eat more food, relative to their weight, and consume much larger quantities of fruit, which has a high likelihood of being contaminated with pesticides. Fruit comprises 20 percent of the adult diet and 34 percent of the preschooler's diet. Preschoolers eat six times as much total fruit, seven times more grape products and seven times more apples and applesauce, relative to their weight, than adults. Apple juice is a particular favorite of children. The typical preschool child consumes almost 18 times as much apple juice and the typical toddler more than 31 times as much apple juice, relative to their weight, as the average adult woman.

Fruit is highly likely to contain pesticide residues. The 1987 FDA's food monitoring program found that 50 percent of all fruit samples had detectable levels of pesticides. This residue rate is higher than that of any other commodity and may significantly underestimate the full extent of residues because FDA's monitoring program does not routinely monitor for nearly half of the pesticide residues in food.

NRDC's analysis of exposure, based on a USDA study of food consumption by children and women, determined that relative to their weight preschoolers receive much greater exposure than adults to the majority of the pesticides analyzed in this report. The average preschooler receives more than five times greater exposure to the fungicide mancozeb, nine times greater exposure to the neurotoxic organophosphate azinphos-methyl and 12 times greater exposure to UDMH, the carcinogenic metabolite of daminozide, than adults. The typical preschooler receives four times greater exposure, on average, than adults to the eight carcinogenic pesticides evaluated. The youngest children receive the greatest pesticide exposure. Relative to adult women, toddlers

receive more than eight times the exposure to mancozeb, 15 times greater exposure to azinphos-methyl and 18 times greater exposure to UDMH, than women.

B. S. 1074 REQUIRES THAT EPA ACCURATELY ASSESS EXPOSURE.

S. 1074 strengthens the federal pesticide regulatory program by requiring a more accurate assessment of exposure to pesticide residues as a prerequisite to a new pesticide tolerance. The bill requires that a pesticide legal limit take into account the other uses of the same pesticide on food and the other exposures to the pesticide the consumer experiences through the diet (such as through drinking contaminated water). These provisions are vital if the pesticide limits are to reflect the actual exposures experienced by our citizens.

The bill requires that exposures be evaluated on the assumptions that all commodities on which the pesticide's use is legal are treated with the pesticide, that the residue levels equal the pesticide tolerance level, and that exposure at the legal limit is likely to occur over a lifetime. These are reasonable assumptions which are necessary to ensure that the exposures of some members of society are not being ignored. The bill provides an exception whenever EPA has reliable data showing that less of the crop is treated and that the treated portion of the crop is distributed in a way which ensures that the risk is distributed evenly among consumers of the commodity.

EPA has not routinely lowered tolerances upon a finding that the legally permissible concentrations of pesticide residues would cause high risk of cancer or other adverse effects. EPA often dismisses these findings by stating that residues are normally below tolerance levels, but EPA does not concomitantly lower the tolerances to what it has declared to be the "normal" level. Consequently, people today may unwittingly consume foods that, although legal, contain pesticide levels which EPA's data demonstrate to be unsafe.

Legal food should be safe food. Without prohibitively expensive chemical analyses of all food, consumers cannot identify which foods bear high residues and which have lower, safe concentrations of pesticides. Therefore, EPA should ensure that consumption of food with residues at the legal maximum is, in every case, safe. EPA should perform risk assessments based on the assumption that pesticide residues will be present at the maximum legal concentration. If EPA, growers or the food industry believe that such a risk assessment overstates the risk, they should demonstrate that actual residues are lower and petition for a lower legal limit. This is how S. 1074 would function. The bill in effect requires EPA to limit pesticide residues to the level EPA calculates will result in no more than a negligible risk to any consumer of the food.

C. S. 1074 REQUIRES THAT EPA ESTABLISH PRACTICAL METHODS OF ANALYSIS FOR ALL PESTICIDES.

Pesticides should not be used on food if FDA cannot readily detect the residues in food. Without the ability to detect residues at reasonable cost, FDA cannot enforce EPA's tolerances and therefore cannot protect the public from pesticide residues in food. S. 1074 recognizes this fact and corrects the current anomalous situation in which dangerous pesticides are used on food or which government agencies cannot routinely find by their monitoring methods.

FDA monitoring for pesticides is inadequate to ensure that residues are legal, let alone safe. Of the 496 pesticides FDA has identified as likely to leave residues in food, FDA's routine analytical methods can only detect 203 -- only 41 percent.[12] Of the 105 pesticides which FDA considers to pose a moderate to high health hazard, only 58 (55 percent) are detectible using the FDA multi-residue methods.[13] Among the commonly used pesticides which cannot be detected by

12. GAO, Pesticides: Need to Enhance FDA's Ability to Protect the Public from Illegal Residues, October 1986, p. 33.

13. Ibid, p. 36.

FDA's multi-residue methods are benomyl, daminozide, the EBDC fungicides and paraquat.[14] Twenty-six of the 53 pesticides identified by EPA as potentially oncogenic for the 1987 NAS report on pesticides in food cannot be detected by FDA's multi-residue method.

EPA should require that manufacturers of pesticides used on food develop practical methods for detecting pesticide residues. An analytical method should be considered practical only if the method: (1) reliably and routinely quantifies the level of residue in food with sensitivity sufficient to enforce the tolerance; (2) provides results in less than eight hours; (3) can be used in FDA labs with existing FDA laboratory equipment; and (4) costs no more than what is typically incurred by the FDA in using a multi-residue method. The bill would encourage the development of multi-residue methods for a wider range of pesticides. S. 1074 would greatly improve FDA's ability to enforce the pesticide tolerances.

D. S. 1074 REQUIRES THAT PESTICIDE "INERT" INGREDIENTS HAVE TOLERANCES UNLESS THEY ARE CHEMICALS WHICH POSE NO SIGNIFICANT RISK.

The federal pesticide law distinguishes between active ingredients, which kill, repel or otherwise control pests, and so-called "inert" ingredients, substances which are used to dilute, propel or stabilize the active ingredient.[15] In many instances, the non-active ingredients are extremely toxic chemicals.[16] EPA has broadly exempted all of these "inert" ingredients from regulation under the FDA. NRDC believes that current law requires EPA to set tolerances for

---

14. Ibid, p. 39.

15. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136(a) and §136(m).

16. EPA has listed 57 inert pesticide ingredients "of toxicological concern." 52 Federal Register 13305, April 22, 1987. Included on EPA's list were extremely dangerous chemicals, some of them restricted or cancelled for use as active ingredients by EPA, such as benzene, carbon tetrachloride, chloroform, formaldehyde, and mercury oleate.

these ingredients. However, we fear that litigation may be necessary to motivate EPA to set tolerances for these dangerous pesticide ingredients.

S. 1074 requires EPA to revoke the food uses of dangerous "inert" ingredients unless they have a tolerance which ensures that they pose no more than a negligible risk. This provision would greatly enhance food safety. Because many so-called inert ingredients today are actually toxic chemicals, there may be instances in which the pesticide may pose excessive risks not because of the active ingredient but instead because of the substance used to dilute, propel, or stabilize the formulation.

Inert ingredients are generally not essential to the pesticide product. If a manufacturer wants to continue to use the active ingredient in or on food, the manufacturer should substitute an innocuous ingredient for the one posing a significant health threat. If an entirely innocuous ingredient cannot be found, the pesticide manufacturer must have the burden of testing the ingredients and demonstrating that, at the tolerance level, they will pose no more than a negligible risk in combination with the active ingredients. EPA should never allow residues of an inert ingredient to pose a significant health hazard.

E. THE BILL PROVIDES EPA WITH EXPLICIT AUTHORITY TO IMMEDIATELY REVOKE OR MODIFY TOLERANCES WHEN NEEDED TO AVERT AN "IMMINENT HAZARD."

In 1988, EPA Assistant Administrator Dr. John A. Moore testified before the House Energy and Commerce Committee this Committee that under current authorities, EPA's revocation of a tolerance due to a registrant's failure to submit data promptly is labor-intensive and time-consuming. He suggested that revocation, when challenged by registrants, may take at least two

years.[17] Dr. Moore expressed the need for a provision in the law automatically revoking tolerances where data-submission deadlines are missed.[18] NRDC believes that food safety legislation should contain provisions automatically revoking tolerances if required data are not submitted in accordance with statutorily defined deadlines. S. 1074 appropriately provides this necessary authority.

V.

S. 1074 NEEDS STRENGTHENING IN ORDER TO ENSURE THAT PESTICIDES IN FOOD DO NOT ENDANGER PUBLIC HEALTH. NRDC WILL OPPOSE ENACTMENT OF ANY BILL WHICH WOULD ERODE THE PURELY HEALTH-BASED STANDARD OF S. 1074 OR WEAKEN STATE POWERS OVER PESTICIDES.

A. NRDC URGES THE COMMITTEE TO ADOPT AN AMENDMENT TO REQUIRE THE ELIMINATION OF ALL PESTICIDES WHICH ARE PROBABLE HUMAN CARCINOGENS BY THE YEAR 2000.

Even though S. 1074 will help to reduce residues of carcinogenic pesticides in food, NRDC believes the bill should ultimately eliminate use of pesticides which are probable human carcinogens. Though the bill is an excellent interim measure, there are reasons to phase out all substances which EPA believes are likely to cause cancer in humans. First, the new tolerances which would be developed under the bill rely on risk assessment, which may understate the risk certain pesticides pose for humans. Furthermore, the bill does not ensure that cumulative, lifetime exposures to the hundreds of pesticides in every American's diet are safe. Finally, the public needs assurance that, even if federal agencies' implementation of the new law is no more diligent than their implementation of the old law, the public will ultimately see a substantial

17. Testimony of Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, Regulation of Pesticide Hearing, House Energy and Commerce Committee, June 8, 1987, p. 172.

18. Ibid, p. 178.

reduction in the use of carcinogenic pesticides. Particularly given the ubiquitous and often involuntary exposure to other, non-pesticidal carcinogens -- from radon and cigarette smoke to automobile emissions -- NRDC considers it imperative that Congress take steps to minimize each person's exposure to pesticides and other substances which are carcinogens.

NRDC therefore strongly urges this Committee to require EPA to revoke tolerances for all pesticides which authoritative federal agencies -- such as the EPA, the National Cancer Institute, or the National Toxicology Program -- identify as "probable human carcinogens." Alternative pest control methods should be sought for such substances. Unless there is a Congressionally-mandated deadline for eliminating these dangerous pesticides, pesticide manufacturers and growers will have no incentive to develop innovative crop protection processes as alternatives to carcinogenic pesticides. To allow for the time needed to conduct research in pest management to establish such alternatives, NRDC would be willing to delay the application of such a provision for a number of years. Nevertheless, the American people deserve the assurance that by the year 2000 the foods they consume will not contain any pesticide which has been identified as a probable human carcinogen.

B. NRDC'S SUPPORT FOR S. 1074 IS CONTINGENT ON REJECTION OF "ECONOMIC BENEFITS" AS A JUSTIFICATION FOR ALLOWING PESTICIDES IN FOOD TO POSE GREATER THAN A NEGLIGIBLE RISK.

Tolerances should be set at safe levels. Legal food must be safe food. Economic benefits of the pesticide are irrelevant to the question of how much residue in food is safe. EPA currently interprets FFDCA section 408 as enabling the Agency to balance the risks of pesticide with the benefits of the chemical.[19] NRDC believes such an interpretation is unsupported by the statute, legislative history, or legal precedents. EPA testified before the House Energy and

19. Testimony of John A. Moore, June 8, 1987, supra, p. 170.

Commerce Committee in 1989 in favor of authority to grant tolerances for dangerous pesticides based on considerations of benefits.[20]

Benefits considerations can become an enormous loophole to the strict regulation of widely used but extremely dangerous pesticides. Those familiar with EPA's implementation of the FIFRA statute have witnessed EPA repeatedly cite economic benefits as the justification for continuing the registration of very hazardous pesticides. Benefits analyses appear to be developed in the absence of reliable data and almost invariably result in retaining dangerous uses. Many of these analyses rely on unsubstantiated claims from the manufacturers or users about the usefulness of the chemical. Seldom does the EPA consider that non-pesticidal crop protection strategies may serve as an alternative to pesticide use. "Economic benefits" to the pesticide industry or to growers, and particularly not the current highly subjective analyses of supposed benefits, should not be used to justify hazardous residues in our diets.

C. NRDC'S SUPPORT FOR S. 1074 IS CONTINGENT ON CONGRESS' REJECTION OF ALL EFFORTS TO PREEMPT STATE AUTHORITY TO SET STRICTER PESTICIDE TOLERANCES.

Proponents of amendments which would preempt states' authority to set tolerances say that such amendments are needed to prevent a "crazy quilt" of conflicting legal requirements which complicate or interrupt interstate commerce of agricultural produce. Unfortunately, this assertion lacks an empirical foundation. Experience has revealed that states exercise their authority to set more stringent pesticide tolerances cautiously and only in compelling circumstances.

States have acted to set more stringent tolerances only when faced with extreme federal inertia in the face of ample evidence that public health was not adequately protected by federal

---

20. Testimony of John A. Moore, Acting Deputy Administrator, Environmental Protection Agency, before the Committee on Energy and Commerce, Subcommittee on Health and the Environment, May 15, 1989.

tolerances. There are approximately 300 pesticides approved for uses on food. Only two pesticides have been the subject of state efforts to tighten federal tolerances: ethylene dibromide (EDB) and daminozide (Alar).

In both instances where states set tolerances more stringent than the federal limits, many years of federal inaction or ineffective efforts preceded state action. In both instances, compelling evidence was available on the basis of which state health authorities concluded that the risks from these pesticides were great, particularly for children. Both times the states tried to motivate the federal government to act and probably would have preferred swift and decisive federal action. The EDB and daminozide incidents did not stem from a surplus of conflicting and overlapping authorities to set tolerances. Instead, these events demonstrate the confusion and danger which result from the federal government's failure to exercise its authority to revise tolerances when new data reveal high risks. State authority must be retained as a "fail safe" in the event that the federal government fails to diligently and effectively implement the food safety law.

VI.

CONCLUSION

NRDC applauds the Chairman for this important piece of legislation to ensure that pesticides in food are safe. Legislation of this kind is urgently needed to restore public confidence in our federal programs to protect our food supply. We urge the Committee to challenge those who maintain that this bill would result in enormous losses to agriculture to provide data to support their claims. NRDC believes that there is no evidence indicating that setting pesticide tolerances at a safe level would result in food scarcities or higher consumer prices for nutritious commodities. This bill does not require the banning of pesticides whenever they pose any risk. Instead, the bill wisely requires residues of dangerous pesticides to be limited to a level which is safe for all members of society. This bill would require EPA to phase out the uses

of pesticides only when the chemicals are so dangerous that they cannot be used in agriculture effectively at levels which pose less than a negligible risk to the public. The American public is demanding a vastly safer food supply. We hope to work with this Committee to ensure that the public's demand is heeded.

The CHAIRMAN. Thank you very much.

Mr. Guardia.

Mr. GUARDIA. Mr. Chairman and members of the committee, I am Enrique Guardia, vice president of scientific relations for Kraft General Foods, which is the largest manufacturer of processed foods in the United States.

I am testifying today on behalf of the National Food Processors Association, NFPA. Accompanying me is Clausen Ely, with the firm of Covington and Burling, legal counsel for the association.

Let me stress at the outset that NFPA recognizes the need for pesticide tolerance legislation, and we are prepared to work toward enactment of this reasonable tolerance bill in this Congress.

In January of this year, the NFPA announced the comprehensive food safety legislative proposal to improve regulation of pesticide residues in food. The overriding goals of the NFPA proposal are to establish a consistent and scientifically defensible pesticide safety standard, to simplify and streamline pesticide cancellation and tolerance procedures, and to mandate national uniformity for tolerances meeting current safety standards.

We support the provisions of S. 1074 that would harmonize the safety standards for pesticide residues in rural and processed foods that would permit sale of food treated with a pesticide for which a tolerance is later revoked and that would assure an open and timely tolerance setting process.

NFPA has made clear its support for a uniform negligible risk standard for pesticide residues in raw and processed food, but not at the expense of scientific reason, regulatory order or consumer welfare.

The NFPA has one of the best pesticide residue data banks for processed foods, and its data along with FDA, USDA and the State of California have shown that pesticide residues in processed foods are far below tolerance levels, are significantly reduced from levels containing raw ingredients, and are ordinarily undetectable.

Now I will address the specific features of the bill that are of greatest concern to our members.

Negligible risk standards. S. 1074 would impose a prescriptive and highly conservative definition of negligible risk. This would foreclose considerations of scientific advances and restrict regulatory flexibility in the same manner as the Delaney clause. Arbitrary numerical risk standards should not be case in statutory stone.

Dietary exposure calculations. S. 1074 would require EPA to assume that residues occur in 100 percent of crop for which the pesticide is approved and at full tolerance levels. Food industry and FDA studies have shown that these assumptions are simply false.

The worst case exposure assumptions required under S. 1074 would reduce the incentive for farmers to minimize pesticide use.

Benefits. S. 1074 would eliminate any consideration of benefits in pesticide tolerance decisions. We strongly oppose this aspect of the bill because the proposed prohibition of consideration of benefits in pesticide tolerance decisions is fundamentally inconsistent with FIFRA and in effect would amend FIFRA for all food use pesticides.

Also, food use pesticides contribute important health benefits that can outweigh the hypothetical risks attributed to consumptions of residues. Pesticides provide direct health benefit through control of disease-carrying insects, harmful molds such as aflatoxins, and other toxins.

Pesticides also play an essential role in providing a wholesome, healthy and nutritious food supply. The methodology for negligible risk determinations include multiple uncertainties and conservative assumptions. Because of these assumptions, the calculated one in one million lifetime risk is equivalent to an extremely low risk or no risk at all. It is thus appropriate for EPA to retain authority to take into account the benefits of pesticides that pose greater than a hypothetical one in one million risk.

The bottom line is that without pesticides we will not have an adequate, wholesome and economic food supply.

Tolerance and uniformity. The bill fails to address the need for uniform tolerances for pesticides that have been shown to be safe under current EPA regulations. Permitting different and inconsistent State and local tolerance causes public fear and confusion, disrupts interstate commerce, creates barriers to international trade, and undermines EPA's regulatory authority.

In conclusion, while we support the eliminating of the Delaney clause to pesticide residues in processed foods, S. 1074 contains a multitude of false assumptions that would make tolerance decisions arbitrary and overly restrictive, would inhibit sound science, and would make the minor use problem even worse.

NFPA is strongly committed to reasonable pesticide tolerance legislation, but we cannot support the proposals embodied in S. 1074 as introduced. We are prepared to work with the Congress in fashioning reasonable legislation.

Mr. Chairman, the American people demand and deserve an adequate, wholesome and economical food supply, and this is only possible with a reasonable, scientifically based pesticide policy.

Thank you.

[The prepared statement of Mr. Guardia follows:]

PREPARED STATEMENT OF DR. ENRIQUE J. GUARDIA

Mr. Chairman and members of the committee, I am Enrique J. Guardia, Vice President of Scientific Relations for Kraft General Foods, the largest manufacturer of processed food in the United States. I am testifying today on behalf of the National Food Processors Association (NFPA). Accompanying me is Clausen Ely, with the firm of Covington & Hurling, legal counsel to the Association. We appreciate the opportunity to appear today and to address the important and timely topic of the safety of pesticide residues in food.

I hold a Ph.D. in biochemistry, and have served in scientific and research capacities in the food industry for over 25 years. My responsibilities have comprised scientific research, regulatory compliance and quality control, including issues relating to risk assessment and control of pesticide residues in food.

NFPA is a national trade association representing over 500 companies, including food processors, and food packaging and equipment manufacturers. NFPA maintains three research laboratories, employing over 100 scientific personnel, which conduct a wide range of important food processing research. NFPA laboratories are widely recognized as leaders in pesticide residue testing, and NFPA maintains an extensive pesticide residue data bank.

NFPA maintains active programs to assure that processed foods do not contain illegal or excessive pesticide residues, to develop pesticide use and residue data necessary for accurate and realistic benefits and exposure assessments, and to promote Integrated Pest Management (1PM) and other techniques to minimize pesticide use.

The NFPA Pesticide Screen Program has been widely used in the food industry for many years for optimum quality procedures for controlling pesticide residues in food. The emphasis of the Pesticide Screen Program is on measures to assure proper use of pesticides by growers of crops employed in processed food. The Program includes regular communication between processors and growers to assure prudent and legal pesticide use, establishment of procedures for maintenance of accurate pesticide use records and participation in education programs on proper pesticide use.

Let me stress at the outset that NFPA recognizes the need for pesticide tolerance legislation, and we are prepared to work toward enactment of a reasonable tolerance bill in this Congress. In January of this year, NFPA announced a comprehensive food safety legislative proposal to improve regulation of pesticide residues in food. The NFPA proposal builds upon the recommendations of the 1987 National Academy of Sciences (NAS) Delaney Paradox Report and is consistent with President Bush's food safety plan submitted to Congress last year. The overriding goals of the NFPA proposal are to establish a consistent and scientifically defensible pesticide safety standard, to simplify and streamline pesticide cancellation and tolerance procedures, and to mandate national uniformity for tolerances meeting current safety standards.

NFPA supports the following specific legislative provisions, which will provide a solid foundation for assuring the availability of safe and beneficial pesticides in the coming decades.

(1) A uniform negligible risk standard for pesticide residues in both raw and processed food.

(2) A requirement that EPA employ actual pesticide use and residue data in calculating dietary exposures.

(3) Continuation of the requirement that EPA conduct a- risk-benefit analysis in determining whether to issue or revoke a pesticide tolerance.

(4) National uniformity of pesticide tolerances approved by EPA since 1985, with limited provision for special State tolerances justified by compelling local conditions.

(5) A requirement that EPA adopt CODEX-recommended maximum pesticide residue levels (MRL's) unless there are valid scientific reasons for not doing so.

(6) A pipeline provision that would permit sale of existing stocks of food legally treated with a pesticide for which the tolerance is subsequently revoked, unless EPA can establish that the remaining stocks of food pose an unreasonable dietary risk.

(7) Elimination of the cumbersome and time-consuming adjudicatory hearing requirement in the pesticide cancellation process.

(8) Required periodic—renewal of pesticide registrations and tolerances to assure continued evidence of pesticide safety.

While we recognize Chairman Kennedy's effort in developing a bill to address pesticide tolerance issues, the bill is inconsistent with many of NFPA's stated objectives and would not advance the public interest.

We support the provisions of the bill that would harmonize the safety standards for pesticide residues in raw and processed food, that would permit sale of food treated with a pesticide for which a tolerance is later revoked, and that would assure an open and timely tolerance setting process. Much of the bill, however, is contrary to the interests of the food industry and consumers, and is not an improvement over current law. The bill goes far beyond the recommendations of the HAS and the recognized need to streamline the pesticide tolerance process. The bill would mandate a rigid and unrealistic negligible risk standard, would unduly limit EPA's scientific and regulatory discretion, would disrupt the FIFRA reregistration process and would prohibit EPA from considering any health or consumer benefits in pesticide tolerance decisions. An important adverse effect of this approach would be to accelerate the loss of safe and effective minor use pesticidesl which are of particular importance to our members. On balance, the bill creates many more problems than it solves, and we can not support it.

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

Before addressing S. 1074, I would like to stress several important points. First, our members are committed to undertake all reasonable efforts to assure that their products contain no illegal pesticide residues and that pesticide use is reduced to the

extent feasible, through Integrated Pest Management and other steps. Our surveys and those of the United States Department of Agriculture (USDA) and other agencies show that farmers carefully limit pesticide use to well below maximum permitted application rates and that pesticides are only applied to the percentage of the crop for which a real need is demonstrated.

Second, numerous studies conducted by our labs, the Federal Food and Drug Administration (FDA) and other agencies have demonstrated that pesticide residues in processed foods are far below tolerance levels, are significantly reduced from levels contained in raw ingredients and are ordinarily undetectable. For example, the California Department of Food and Agriculture conducted extensive surveys-in 1987 and 1988 that showed that over 82 percent of crops grown for processing had no detectable pesticide residues. Moreover, it is important to bear in mind that the critical consideration for risk analysis is the level of pesticide residues in food as eaten. For raw fruits and vegetables, consumers ordinarily undertake preparation, including washing and trimming, that reduces any pesticide residues prior to consumption.

Third, NFPA supports strong and effective pesticide tolerance laws and allocation of sufficient resources to permit the Environmental Protection Agency (EPA) and FDA effectively to implement and enforce those laws.

Finally, there should be no consideration of pesticide tolerance legislation without serious attention to the potential impact on minor uses. Unfortunately, S. 1074 would exacerbate, rather than relieve, the minor use problem. The growing loss of minor use pesticides for fruit and vegetable production poses a serious problem for the food industry. Minor uses are not economically attractive to the pesticide industry, and there is little incentive for pesticide producers to underwrite the high cost of defending these uses. The 1988 FIFRA Amendments require that all pesticides registered prior to 1984 be reregistered over a 9-year period. For reregistration, pesticide producers must develop extensive safety, environmental and residue studies to support each registered use, and must pay substantial fees to fund EPA's reregistration program. Because of the costs involved, a growing number of producers are abandoning minor use registrations, without regard for the relative safety or benefits of those uses.

Two recent examples of the serious dimensions of the minor use problem are the threatened loss of many valuable uses of the ethylene bisdithiocarbamate (EBDC) fungicides and of the—insecticide Malathion. The pesticide producers have decided to abandon support for these minor use registrations to avoid testing costs and, in the case of some EBDC uses, to assure that all major uses are retained without exceeding a negligible risk level. These decisions are made without any consideration of the benefits of the abandoned minor uses to consumers and the agricultural community.

EPA and USDA released a joint statement on April 15, 1991 regarding the importance of reregistration of minor uses. The statement stresses that minor use pesticides are of major significance to agricultural production and consumers, that many fruits and vegetables could not be grown successfully without minor use pesticides1 and that measures must be adopted to assist in preservation of minor uses. S. 1074 would undercut the Agencies' efforts and would aggravate the minor use problem by eliminating consideration of benefits in tolerance decisions, by prescribing rigid and unduly conservative safety standards and by increasing the costs of supporting minor use registrations.

With this background, I would like to address several specific features of the bill that are of great concern to our members. Without substantial improvements in these aspects of the legislation1 the public interest would be better served under current law.

1. NEGLIGIBLE RISK STANDARD

Although S. 1074 would eliminate application of the Delaney Clause to pesticide residues in food, it would impose a prescriptive and highly conservative definition of negligible risk. This would foreclose consideration of scientific advances and restrict regulatory flexibility in the same manner as the Delaney Clause. Instead, EPA should be permitted to take into account all relevant scientific information in making negligible risk determinations, and arbitrary numerical risk standards should not be cast in statutory stone.

Under S. 1074, a negligible risk for non-threshold pesticides, including those that cause cancer in man or animals, would be defined as a one in a million lifetime risk, with a special standard of one in a million divided by 70 for any single year of exposure during the first 5 years of life of an exposed person. EPA also would be required to use the most conservative risk assessment models and to calculate a sepa-

rate risk for seven specific age groups of infants and children (e.g., 0 to 1, 1 to 2, etc.). This rigid definition of negligible risk would preclude EPA from taking into account biological data on mechanism of action and other relevant scientific information. This would squeeze EPA into a regulatory straitjacket and abandon science in favor of arbitrary limits.

2. DIETARY EXPOSURE CALCULATIONS

Under current law, EPA is free to employ any scientifically defensible exposure data in making pesticide tolerance decisions. Although EPA often employs conservative exposure assumptions, it is free to use, and has used, actual pesticide use and residue data for dietary exposure calculations. By contrast, S. 1074 would require EPA to assume that residues occur in 100 percent of commodities for which treatment is legal and at full tolerance levels. Food industry and FDA studies have shown that these assumptions are false.

S. 1074 would permit calculation of dietary exposure on the basis of the percentage of a commodity actually treated under only one narrow exception. EPA would be required to show that the percentage of food containing residues is not likely to increase significantly in the subsequent five years, that "the national distribution of such percent of such food does not vary significantly from the distribution of the total amount of such food," and that the aggregate risk from all pesticide residues on the food are negligible. This would establish a virtually insurmountable evidentiary barrier to use of actual crop treatment data. Moreover, the bill would bar use of actual residue data, in lieu of tolerance levels, under any circumstances1 regardless of the quality of available residue data or the difference between actual residues and the tolerance level.

As noted, there are extensive government and food industry studies on the levels of pesticide residues in food. The United States Department of Agriculture is currently undertaking, at Congressional direction and substantial taxpayer expense, a large survey of pesticide residues in food. This type of information, regardless of its accuracy and statistical significance, would be rendered useless by S. 1074.

The worst case exposure assumptions required under S. 1074 would reduce the incentive for farmers to minimize pesticide use and would precipitate regulatory action against valuable pesticides for which there are reliable data demonstrating a negligible exposure risk.

3. BENEFITS

S. 1074 would eliminate any consideration of benefits in pesticide tolerance decisions. We strongly oppose this aspect of the bill. EPA is currently required, in making pesticide tolerance decisions, to give appropriate consideration to the necessity for the production of any adequate, wholesome and economical food supply. This provision is fully appropriate and should be retained. There are several important reasons why retention of' benefits considerations in pesticide tolerance decisions is desirable.

First, EPA is required under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to balance the risks and benefits of pesticide use, and to consider the impact of registration decisions on the production and prices of agricultural commodities. The proposed prohibition of consideration of benefits in pesticide tolerance decisions is fundamentally inconsistent with FIFRA and would nullify the benefits feature of FIFRA for all food use pesticides.

Second, food use pesticides provide important benefits for American agriculture and consumers. Pesticides help make available to United States consumers a wide range of high quality and affordable food products. Without effective pesticides, food quality would be reduced and prices increased, with disproportionate adverse impact on low income consumers. Pesticides enhance agricultural production and income, and provide support for the international competitiveness of United States food producers. Prohibition of benefits assessments in tolerance decisions would harm both United States agriculture and consumers.

Third, food use pesticides contribute important health benefits that can outweigh the hypothetical risks attributed to consumption of residues. Pesticides provide direct health benefits through control of disease-carrying insects, harmful molds (such as aflatoxin)and other toxins. Pesticides also play an essential role in providing a wholesome, healthy and nutritious food supply. The Department of Health and Human Services (HHS), the Surgeon General, other government agencies, and prominent scientific and medical organizations have increasingly stressed the value of a balanced and nutritious diet, including ample amounts of fresh fruits and vege-

tables, in maintaining health and preventing disease. The loss of an important food use pesticide can decrease crop yield, damage crop quality, increase food costs and eliminate the availability of certain types of foods. This can have a significant adverse effect on the health and nutrition of consumers. EPA should be required to take these important health consequences into account in making pesticide tolerance decisions. Although pesticide benefits can not be quantified with absolute precision, there are greater uncertainties in pesticide risk assessments. Moreover, as noted, risk calculations are based on numerous worst case assumptions.

Finally, consideration of benefits in food regulatory decisions is not unique to pesticide tolerance determinations. Benefits are also integral to FDA's regulation of environmental contaminants in food. Under section 406 of the FD&C Act, FDA has authority to set tolerances or action for substances that are required levels in the production of food or that cannot be avoided under good manufacturing practice. It is well established that FDA may take into account the benefits of food containing environmental contaminants, in terms of the likely economic losses from destruction or unavailability of that food, in fixing tolerances or action levels.

The methodology for negligible risk determinations include multiple uncertainties and conservative assumptions. Because of these assumptions, a calculated one in a million lifetime risk is equivalent to an extremely low, or nonexistent, actual risk. It is thus appropriate for EPA to retain authority to take into account the benefits of pesticides that pose greater than a hypothetical negligible risk, especially where a pesticide use itself provides health or nutritional benefits.

4. COORDINATION WITH FIFRA

In 1988, Congress established a comprehensive schedule for reregistration of old pesticides to assure that they meet modern data requirements. Food use pesticides are required to be reregistered first, and applicable tolerances are being reevaluated in conjunction with the reregistration of food use pesticides. The FIFRA reregistration process is an ambitious, costly and complicated effort that is straining the resources of EPA and the pesticide industry and that is precipitating the loss of valuable food use pesticides that the producers can no longer afford to support. S. 1074 would superimpose upon the FIFRA reregistration requirements an unnecessary and inconsistent tolerance evaluation scheme and fee structure. This' would impose further burdens on EPA, pesticide producers and the food industry without any compensating benefit to the public.

Under Section 4 of S. 1074, EPA would be required, within one year of the date of enactment, to evaluate all available data with respect to the safety of each pesticide tolerance and exemption. Unsafe tolerances or exemptions would be required to be revoked within one year of such determination. If EPA determined that the available data were insufficient to make a safety determination, it would be required to demand new safety studies and to establish a schedule for submission of such studies that would permit the Agency to make final decisions on 30 percent of tolerances and exemptions within 2 years of the date of enactment, 60 percent within 4 years, 90 percent within 6 years, and 100 percent within 7 years.

The requirements and timetables for generation of data to support pesticide tolerances and exemptions under S. 1074 would be independent of the reregistration requirements under FIFRA. There is no reason to establish separate reevaluation requirements for pesticide registrations and tolerances. Because the tolerance reevaluation requirements under S. 1074 are inconsistent with the FIFRA reregistration requirements, the bill would interfere with, and unnecessarily complicate, EPA's administration of FIFRA. EPA has already indicated that the timetable for pesticide reregistration will be difficult or impossible to meet. The bill's accelerated schedule for tolerance reevaluations will exacerbate EPA's burden in accomplishing an orderly and rational review of food use pesticides.

S. 1074 would authorize EPA to demand additional tolerance fees, including an annual maintenance charge, sufficient to cover the Agency's costs in reevaluating all existing tolerances and exemptions. These fees, on top of FIFRA reregistration fees, would increase the economic pressures on pesticide producers to abandon safe and valuable food use pesticides, particularly for minor crops.

5. TOLERANCE UNIFORMITY

S. 1074 fails to address the need for uniform tolerances for pesticides that have been shown to be safe under the comprehensive data requirements of current EPA regulations. Permitting different and inconsistent state and local tolerances causes public fear and confusion, disrupts interstate commerce and undermines EPA's reg-

ulatory authority. States and local governments should be precluded from issuing special local tolerances or warning requirements unless they can prove that a different standard is justified by compelling local conditions and would not disrupt interstate commerce.

A distinguished Advisory Committee to the FDA (the Edwards Committee) issued a report on May 15th recommending, as an important component of efforts to strengthen FDA, that steps be taken to preempt additional and conflicting state requirements for all products subject to FDA jurisdiction. The same principle should apply to EPA regulation of pesticide tolerances for food.

Inconsistent state and local pesticide residue limits, not only disrupt interstate commerce, but also create barriers to international trade. With the increasing globilization of the food industry and the movement toward uniform food safety standards in the EC and other regions, the United States can not afford to maintain a Balkanized pesticide tolerance system.

CONCLUSION

In summary, the bill takes the sensible and long overdue step of eliminating application of the Delaney Clause to pesticide residues in processed food. Unfortunately, this positive feature of the bill is overshadowed by provisions that would make tolerance regulation more restrictive, would inhibit sound science and would exacerbate the minor use problem. NFPA is strongly committed to reasonable pesticide tolerance legislation, but we cannot support the policies embodied in S. 1074 as introduced. We are prepared to work with the Congress in fashioning reasonable legislation.

The CHAIRMAN. Thank you very much.

Mr. Gardner, with Grocery Manufacturers of America.

Mr. GARDNER. Thank you, Mr. Chairman.

I am Sherwin Gardner, and I represent the Grocery Manufacturers of America, and 80 year-old national trade association comprised of 140 companies that manufacture approximately 85 percent of the packaged foods that are sold in retail stores throughout the United States, and we do appreciate the opportunity to appear here today.

Changes in science and technology since 1954, when requirements were first established for controlling pesticide residues, make it entirely appropriate to review and revise section 408 of the Food and Drug Act to ensure continuation of a high standard of safety for foods and also to make the process of establishing residue tolerances more efficient and effective.

The bill would make the much needed change in the Food, Drug and Cosmetic Act by establishing a negligible risk safety standard for pesticide residues in both processed and unprocessed foods. The National Academy of Sciences recommended such a change in its 1987 report regulating pesticides in food.

GMA supports legislation that would adopt the negligible risk principle recommended by the report, and indeed that principle has broader application to other provisions of the Food, Drug and Cosmetic Act.

Our submitted statement comments on several provisions that are of particular interest to GMA, and I will summarize them very briefly.

First, there is a need for flexible safety standard. The establishment of a negligible risk standard as the bill proposes is consistent with the National Academy of Science recommendations. Regrettably, however, the bill does not establish negligible risk in a way that represents real and meaningful change. In our view the risk determination provisions of the bill are unduly prescriptive. They

would replace one form of an inflexible and unscientific standard the Delaney clause, with another, in which numerical standards and specific evaluation criteria are prescribed.

Second, there is a need for workable processed food tolerance requirements. This bill appears to require the establishment of a separate lower tolerance for residues in processed foods than for unprocessed foods. This is inconsistent with the NAS recommendation for the same single negligible risk standard for processed and unprocessed foods.

Third, there is a need for practical and realistic approaches to exposure and tolerances. The bill would require EPA to calculate dietary exposure on the basis that all foods for which a pesticide is authorized contain residues in amounts equal to the tolerance. This would be inconsistent with actual practice, and studies have shown that not all foods grown are treated and also that residues on those crops that are treated are not present at the full tolerance levels.

Finally, there is a need for national uniformity for pesticide residue controls. Unfortunately, this bill still does not contain much-needed national uniformity language. GMA believes that any fundamental revision in the regulation of pesticide residue tolerances should be applied uniformly throughout the country. No State should be permitted to apply a different standard either directly or indirectly unless it can be shown that due to dietary patterns or other factors peculiar to a State that the Federal standard does not adequately protect the citizens of that State.

In conclusion, Mr. Chairman, GMA agrees that the pesticide residue safety provisions of the Food, Drug and Cosmetic Act need to be modernized to incorporate contemporary scientific standards and to increase the efficiency of the tolerance-setting process. We regret, however, that we cannot support this bill as the vehicle to accomplish that change.

We are, however, ready and willing to work with the committee to fashion a bill that would preserve and enhance the safety of the American food supply and better serve the needs of both the food industry and the general public.

Thank you.

[The prepared statement of Mr. Gardner follows:]

PREPARED STATEMENT OF SHERWIN GARDNER

Mr. Chairman and members of the Committee on Labor and Human Resources, I am Sherwin Gardner, Senior Vice President for Science and Technology of the Grocery Manufacturers of America, Inc. (GMA). GMA is an 80 year old national trade association comprised of 140 companies which manufacture approximately 85 percent of the packaged foods as well as nonfood products sold in retail stores throughout the United States.

GMA has reviewed with great interest the provisions of S. 1074, the Safety of Pesticides in Food Act of 1991. This bill is patterned after similar legislation, S. 722, introduced in the last Congress. Indeed, since 1985, this bill represents the fourth introduction of major legislation intended to bring about needed change in the requirements for regulating the safety of pesticide residues in foods. We recognize efforts in developing these bills and we have seen a narrowing of issues in some areas. Nevertheless, major differences unfortunately remain on important provisions.

The Miller Pesticide Amendments of 1954, which added section 408 to the Food, Drug and Cosmetic Act, constituted a landmark in the history of food regulation. They represented the first requirements for premarket approval of substances found in the food supply, and provided strong assurance to the American public for more

than 30 years that pesticide residues in or on food have not represented a significant risk to health.

Notwithstanding this record of consumer protection, changes in science and technology since 1954 make it entirely appropriate to review and revise section 408 to ensure continuation of a high standard of safety, and also to make the process of establishing residue tolerances more efficient and effective.

In this regard, this bill would make a much needed change in the Federal Food, Drug and Cosmetic Act by establishing a negligible risk safety standard for pesticide residues in both processed and unprocessed foods. The National Academy of Sciences recommended such a change in its 1987 report "Regulating Pesticides in Food." GMA supports legislation that would adopt the negligible risk principle recommended by the report. Indeed, GMA believes that this negligible risk principle also should be adapted for the other Delaney Clause provisions of the Food Drug and Cosmetic Act.

As noted, S. 1074 has narrowed some of the issues. For example, it recognizes the need for a delay in the marketing pipeline for foods when a pesticide residue tolerance is changed or revoked.

Thus, in GMA's view, the bill recognizes some important principles of safety and process. Although we continue to agree that changes in the law are necessary to improve the effectiveness and efficiency of the pesticide residue safety process, we believe that this bill does not present a workable solution to that objective.

Today we wish to focus our comments on a few provisions that are of principal interest to GMA; specifically:

the need for scientifically defensible and workable safety standards;

the need for a single standard for processed and non-processed food tolerances;

the need for a practical and realistic approach to exposure and tolerances; and

the need for national uniformity for pesticide residue controls.

NEGLIGIBLE RISK STANDARD

The bill would establish a negligible risk standard as the basis for establishing safe pesticide residue levels in foods. This approach is consistent with the findings and recommendations of two National Academy of Science reports one on risk assessment, issued in March, 1983, and the other on regulating pesticide residues in food, issued in May, 1987.

We are deeply concerned, however, that S. 1074 does not establish negligible risk in a way that represents real and meaningful change. In our view, the risk determination provisions of the bill are unduly prescriptive. They would replace one form of an inflexible and unscientific standard, the Delaney clause of section 409, with another, in which numerical standards and criteria are prescribed. Further, they would unnecessarily foreclose the consideration of new scientific knowledge or unforeseen events in the production of food.

The NAS report recognized that the Environmental Protection Agency has adopted and is applying conservative, contemporary scientific standards for pesticide residue testing and risk assessment. The application of improved scientific methods should continue to be left to the discretion of the agency, and driven by future scientific development; legislation should not prescribe specific numerical standards nor methods of scientific evaluation.

In addition, S. 1074 fails to provide for consideration of health, nutrition and other consumer benefits in determining whether a tolerance should be permitted for a pesticide in food products. Instead, the legislation should retain the long standing recognition of benefits in the tolerance determination process.

PROCESSED FOOD TOLERANCES

The bill appears to require the establishment of a separate, lower tolerance for residues in processed foods than unprocessed foods. Information demonstrating "the lowest level that occurs if the residue has been removed to the extent possible in accord with good manufacturing practice" is required for petitions to establish a tolerance. This is inconsistent with the HAS recommendation for the same, single negligible risk standard for both processed and unprocessed foods, and would impose additional regulatory burdens on EPA and FDA.

We believe the current provisions of section 402(a)(2), commonly referred to as the "pass through provision", should be retained. This requires that residues in processed foods shall be removed to the extent possible with good manufacturing practices and must not concentrate to a level greater than that approved for the raw

agricultural commodity. In this way, both processed and unprocessed foods would be subject to the same negligible risk standard.

EXPOSURE AND TOLERANCES

In determining what tolerance to establish, the bill would require EPA to calculate dietary exposure on the basis that all food for which the pesticide is authorized contains residues in amounts equal to the tolerance. This would be inconsistent with actual practice; studies have shown that not all foods grown are treated, and that residues on those crops that are treated are not at the full tolerance levels.

Alternatively, the bill would permit the calculation of exposure on the basis of less than 100 percent crop treatment. However, this could only occur where reliable, statistically valid data could forecast future crop treatment and distribution, and if the aggregate risks of all pesticide residues on the food are negligible. These conditions would be virtually impossible to satisfy.

In short, these exposure requirements are unduly conservative and would result in grossly exaggerated and invalid risk projections.

NATIONAL UNIFORMITY

Unfortunately, this new bill still does not contain much needed national uniformity language. GMA believes that any fundamental revision in the regulation of pesticide residue tolerances should be applied uniformly throughout the country. The bill provides that the setting of pesticide residue tolerances be conducted in in open and efficient procedure. It also requires that EPA reevaluate all existing tolerances according to updated scientific standards. Accordingly, once a Federal pesticide residue determination is made, that Federal standard should apply uniformly. No state should be permitted to apply a different standard, either directly or indirectly through warning requirements, unless it can be shown that due to dietary patterns or other factors peculiar to a particular state, that the federal standard does not adequately protect the citizens of that State.

CONCLUSION

In conclusion Mr. Chairman, GMA agrees that the pesticide residue safety provisions of the Food, Drug and Cosmetic Act need to be modernized to incorporate contemporary scientific standards and to increase the efficiency of the tolerance setting process. We regret, however, that we cannot support this bill as the vehicle to accomplish that change:

the negligible risk standards of the bill are overly prescriptive, and the exposure and tolerance setting requirements are unworkable. In addition, the bill lacks provisions to establish national uniformity for residue tolerances that meet new scientific standards.

We are ready and willing to work with the Committee to fashion a bill that would preserve and enhance the safety of the American food supply and better serve the needs of both the food industry and the general public.

Thank you for inviting GMA to participate in this hearing.

The CHAIRMAN. Thank you.

Mr. Vroom.

Mr. VROOM. Thank you, Mr. Chairman.

I believe that you and your committee and NACA's members share three common concerns as we look at this issue of food safety and Federal legislation to address it.

First, we all eat the food grown, with the help of my industry's crop protection products, and we share your concern as individuals and members of our industry about the safety of our food and the continued ability of our industry and our farmer customers and Federal regulators and the food industry itself to continue to improve an already safe food supply.

I personally am the father of two young sons, and have that individual concern that I take home with me every night. I am also part of a family farming operation in Illinois that has a long record

of safe and effective use of pesticides, so I feel like I have a perspective from that side as well.

Second, I think there is room for improvement in the current system both from the legislative and regulatory standpoint.

And third, we believe that the continued safety of America's food supply is of vital importance, and we are prepared to work with this Congress to develop and implement fair and appropriate and effective legislation.

However, we like many others that you have heard from and others who will submit written testimony and input, are not in a position to support S. 1074. We don't see it as a rational or appropriate means to continue to improve an already safe food supply.

Many of the provisions which we believe cannot be fixed in the bill have already been identified as unacceptable by a wide cross-section of the public including farmers and commodity groups, food processors and distributors, and scientists from both the public and private sectors.

I'd like to reduce my additional thoughts here to three areas in the oral statement and appreciate the fact that you will include our full written testimony in the record.

One point would be to address the rigid negligible risk standard that is incorporated into S. 1074; second, the failure of the bill to consider benefits; and third, the unrealistic risk assumptions.

The NAS report, the Delaney paradox, correctly concluded that strict requirements of the Delaney clause actually interfere with measures to reduce cancer risks and block introduction of safer crop protection products. Instead, the report recommended that the Delaney clause be replaced with a de minimis or negligible risk standard. While this bill that you have introduced purports to use a negligible risk standard, we believe that it instead prescribes methods of calculation which would make negligible risk essentially zero risk standard. Therefore we think that that is a distortion of the NAS concept of negligible risk.

Further, in the NRS area, we think that prescription of the "solid bright line" of 10 to the minus 6th in the bill's language versus a somewhat more flexible, narrative negligible risk standard is also a flaw in the bill.

In addition, to make a negligible risk determination, EPA under your bill would be required to take into account the special sensitivities of individuals. We contend that this is part of the current regulatory process and is within the authorization of current law, and to the extent that we can find and you can find and the regulators can find scientific evidence that improvements are needed in the current system, the membership of NACA will support the system changes which we believe can be made via the regulatory channels.

S. 1074 also requires a separate negligible risk calculation for seven specific age groups of infants and children. Yet we are not acquainted with any scientific evidence that would support those particular categories. We think that needs further work and exploration.

I think that provision and the whole area may be premature at this point because of the next NAS report on pesticides in the diet of infants and children that Congress has requested, as yet to be

released but is coming very soon, and would agree with the observations of former Surgeon General Koop, who recently said that to preempt this study at this point in its final hours of preparation would be unwise.

The provision that you've got here under negligible risk standard is especially premature given the fact that EPA currently does account for special groups and again is looking, I think, in cooperation with industry for ways to improve that existing system.

The elimination of benefits in S. 1074, we also have very grave concerns about. First of all, we think it would serve to further create and expand the disharmony between current Food, Drug and Cosmetic Act standards and FIFRA and exacerbate those inconsistencies.

Theoretically under your bill a pesticide that today could get a registration because benefits are used as part of the equation that might outweigh a known risk that is calculated by the agency and the regulators could not get on the market under the provisions of S. 1074, and we believe that your rigid zero risk, negligible risk standard really creates the potential and likelihood that safer pesticides might be more difficult to get onto the marketplace.

Thank you.

[The prepared statement of Mr. Vroom follows:]

PREPARED STATEMENT OF JAY J. VROOM

Mr. Chairman and members of the committee, on behalf of NACA and its member companies, I am pleased to have this opportunity to comment on S. 1074, the "Safety of pesticides in Food Act of 1991."

It is obvious that the authors of S. 1074 have expended a great deal of effort in responding to shortcomings, both real and imagined, with the current system of regulating the permissible level of pesticide residues in America's food supply. NACA's members are this Nation's leading manufacturers of crop protection chemicals. We too eat the food grown with the help of our products1 and we share your concern about the safety of our food.

However, S. 1074 goes far beyond what is needed. Indeed, is difficult to suggest amendments that would fix this bill. Accordingly, NACA must oppose S. 1074. Instead, NACA proposes that we start over with a new bill which addresses attainable goals, which is based on sound science and utilizes realistic risk assumptions, and which is sensitive to both agriculture and the broader public policy issues involved.

Many of the provisions in S. 1074 which NACA believes cannot be fixed have already been identified as unacceptable by a wide cross-section of the public, including farmers, commodity groups, food processors and distributors, and scientists from both the public and private sectors. The flaws in S. 1074 include:

the confusing, rigid and extreme assumptions used in calculating risk assessment;

the bill's failure to consider the benefits from the use of pesticides (which will have a devastating effect on agriculture);

the misguided attempt to regulate all inert ingredients, metabolites and degradation products;

deadlines which are not achievable; and

the many damaging inconsistencies between S. 1074 and current law and practice.

There are other flaws which you and your subcommittee no doubt will hear a great deal more about during and after these hearings. However, do not misinterpret NACA's objections to S. 1074. We believe that the continued safety of America's food supply is of vital importance1 and we are prepared to work with Congress to develop and implement fair, appropriate and effective legislation. We simply do not believe that S. 1074 is a rational or appropriate means to continue to assure a safe food supply. In that regard, we shall now discuss in detail the shortcomings of the proposed legislation.

THE NEGLIGIBLE RISK STANDARD

S. 1074 would replace existing FFDCA standards for tolerance-setting with a new "negligible risk" standard applicable to both raw and processed food. Currently, FFDCA Section 408 (raw commodities) encompasses a risk-benefit analysis (by requiring consideration of "the necessity for the production of an adequate, wholesome and economical food supply), for setting pesticide residues at a level "necessary to protect the public health." Under Section 409, the Delaney Clause bars carcinogenic pesticide residues which concentrate in processed foods. The effect of these two provisions has been discussed, and appropriately criticized, in the National Academy of Sciences' (NAS) report, Regulating Pesticides in Foods: The Delaney Paradox. That report concluded that the strict requirements of the Delaney Clause actually interfere with measures to reduce cancer risks, and block safer product introduction. The report recommended that the Delaney Clause be replaced with a "de minimis" or "negligible risk" standard.

EPA currently sets tolerance levels under Section 409 by using a "de minimis" standard. That standard is described in detail in EPA's October 19,1988 policy, issued in response to the 1987 HAS recommendations, and in their Final Order of February 15, 1991, issued in response to a petition to revoke certain tolerances. EPA's use of that standard results in a workable and logical interpretation of the Delaney Clause, and NACA supports that approach. While S. 1074 purports to use a "negligible risk standard," the bill prescribes methods of calculation which would make "negligible risk" essentially a "zero risk" standard. Therefore, rather than leaving room for discretion to define risk as truly negligible, the bill cleverly defines negligible risk with a no risk standard. This is a distortion of the concept of "negligible risk."

S. 1074 defines a risk as negligible if "exposure to a residue is reasonably certain to cause no harm to human health." In addition, the bill mandates that risk from exposure to residues from non-threshold pesticides is negligible only if the lifetime risk were 1-in-1 million, with a special standard of 1-in-1 million divided by 70 for any single year of exposure during the first five years of life of an exposed person. Neither the HAS nor any of the parties involved in this regulatory process endorses the concept of a fixed numerical value being stipulated in a statute. In testimony before the House Agriculture Subcommittee in 1988, the Executive Director of the HAS Board on Agriculture testified, in part, that:

The NAS committee discussed at virtually every meeting whether to recommend a quantitative benchmark for negligible risk as part of its definition of this important concept. The committee was both sensitive and well aware of valid arguments both for and against specifying a quantitative benchmark in the definition of negligible risk. In the end, the committee was persuaded that quantitative risk estimates of oncogenic risks were too fragile and changeable to either assert that risks below a certain level are truly "negligible"or that risks above the "negligible" level indeed pose a significant risk of cancer in man. Such judgments, in the committee's view, can only be made on a case-by-case basis following a thorough review of the complete toxicological database available on a particular chemical.

The reluctance to fix a numerical value for negligible risk is prudent and understandable knowledge is rapidly advancing in the science bearing on risk assessment, and society needs the flexibility to modify its perception as conditions change, and as views of acceptable risk and the ways to measure it change.

For threshold pesticides, negligible risk is determined using a "no observable effect level" ("NOEL"). The NOEL is the level of exposure at which reliable experimental data, derived from actual exposure to pesticides, show no adverse effects in experimental animals. While a safety factor of tenfold has been recognized among scientific experts as adequate for establishing a safe level of human exposure to cholinesterase pesticides, S. 1074 instead prescribes a 1/100th NOEL (i.e. the NOEL divided by 100) for all risks. A 1/100th NOEL has justification because it provides an extra measure of prudence. For that reason, NACA continues to support the use of 1/100th NOEL for arriving at an Acceptable Daily Intake (ADI). However, when taken in conjunction with the conservative risk assessment model requirements elsewhere in the bill, this level is unreasonably high.

S. 1074 further calls for the use of "conservative" risk assessment models in determining negligible risk, even though such conservative mathematical risk assessment models are not necessarily the most accurate. In making the negligible risk determination, EPA would also be required to take into account the special sensitivities of individuals. No national legislative scheme can be effective if it attempts to set standard for the entire population based on the exceptional needs of a few. This provision alone would bury S. 1074 of its own weight.

The bill does not stop there. It also requires a separate negligible risk calculation for seven specific age groups of infants and children. This provision is premature because the NAS report on pesticides in the diets of infants and children has not yet been released. It would be highly inappropriate at this time to mandate by legislation such specific calculations just months before the results of this important study are made known.

That is not to say that the diets of our children are not currently being considered in the regulatory process. EPA currently accounts for the needs of these groups in setting tolerances. When reviewing petitions to establish a tolerance, EPA considers the special consumption patterns of various age groups. S. 1074, however, has aimed this provision well beyond the necessary mark. Carving such a detailed data requirement scheme in stone only a few months in advance of the very study which will verify the need for such regulation is not legislatively responsible. NACA continues to support the protection of identifiable groups with quantifiable exposure differences. However, we support such legislation only after release and review of the NAS report. In the meantime, this bill's proposed use of conservative assessment models, in conjunction with the truly low definition of negligible risk, offers protection enough to any conceivable population group.

ELIMINATION OF "BENEFITS" FROM CONSIDERATION

EPA is currently required to consider both the risks and benefits of pesticide use in registering pesticides under FIFRA. Benefits of a pesticide may also be considered in granting raw commodity and processed food tolerances under FFDCA. Only the Delaney Clause implicitly prohibits consideration of pesticide benefits for carcinogens. S. 1074, however, eliminates all consideration of benefits in setting tolerances in all foods. Rather than resolving the inconsistency between the two statutes prompted by the Delaney Clause, the Act actually exacerbates that inconsistency. Under S. 1074, a pesticide could receive a FIFRA registration because the benefits of its use are such that they outweigh a known risk. Yet that same pesticide may fail to receive a tolerance because the risk exceeds the (now zero-level) negligible risk standard, and because the benefits are not considered. The incongruous result is that a pesticide could lawfully be sold and applied under FIFRA, but the treated produce or crop would be illegal under FFDCA. By eliminating all consideration of benefits under FFDCA, S. 1074 has merely substituted one paradox for another.

But S. 1074 has an even more basic bailing. Consideration of pesticide benefits, along with their risks, is good public policy and an appropriate consideration for making regulatory decisions on pesticides. In the context of FFDCA, decisions on permissible pesticide residues are directly related to the ability of agriculture to provide inexpensive and quality food, and to the ability of others to provide clean and healthy eating, working and living conditions. However, in no case should a benefits analysis allow an otherwise dangerous product to reach, or stay on, the market. The key is balance and informed, rational decision making, concepts which this bill's silence on the benefits issue will frustrate.

The benefits from use of pesticides in assuring a safe, wholesome and abundant food supply are important, relevant factors for consideration. They include:

Pesticides provide America's farmers with a strategic resource in the battle to control pests that would otherwise cause widespread and significant damage to almost all crops grown in the United States. They allow for selective control of harmful insects, nematodes, weeds, rodents and plant pathogens. In the pest management context, insecticides are the only practical control measure for insect pest populations approaching or at infestation levels that will cause major crop damage or health risks. They have rapid curative action, offer a wide variety of uses and methods of application, are low in cost, and are associated with substantial labor savings to growers.

Pesticides lead to increased availability, lower prices, and improved quality of commodities, especially fruits and vegetables. At a time when malnutrition and hunger are no longer solely remote problems of the third world, this benefit is of increasing importance. The availability of a wide variety of food all year is an invaluable benefit to the public.

Yet even these facts do not tell the real benefits from use of pesticides. Protection from the devastation of entire local and regional crop loss is available from judicious use of crop protection chemicals. In many areas and on many crops, pesticides are the only means to control pests whose presence would otherwise prohibit production of certain crops. Without these tools to protect crops, many individual farms may fail. For example, most fruits and vegetables simply cannot be produced in most parts of the eastern and southeastern United States without insecticides and

fungicides. This fact was even acknowledged by the NAS Alternative Agriculture study, and by an eminent organic farmer (Ward Sinclare), who stated that he can't produce organic potatoes on his farm in Pennsylvania because he can't control the Colorado Potato Beetle without insecticides.

In current practice, EPA, correctly, does not place primary importance on benefits analysis. According to the March 7, 1991 GAO report on EPA's use of the benefits assessment, the agency "bases initial tolerance and registration decisions primarily on perceived risks to health and on environmental considerations....the principal role of benefit analysis is to inform EPA decision makers during special review ... about the extent of the benefits associated with a specific pesticide's use." However, by eliminating these important considerations, the agency will be required to make tolerance and registration decisions in a vacuum.

EXPOSURE ASSUMPTIONS

EPA is free under current law to employ any reasonable and scientifically defensible exposure data in making pesticide tolerance decisions. Although EPA often employs conservative exposure assumptions, it is free to, and has used, actual residue data for exposure calculations where reliable and accurate information is available. S. 1074 would virtually prohibit use of such data.

The risk posed by a substance depends both on its affect and exposure to it. In essence, no exposure means no risk. S. 1074 not only assumes that there is always exposure to a pesticide—a bold and inaccurate assumption—but also assumes the most extreme case. In calculating exposure to a pesticide S. 1074 requires EPA to make the following assumptions and considerations:

The residue occurs in 100 percent of commodities for which treatment is legal,
All crops have the maximum permitted residue,
The residue is consumed for a lifetime,
All other dietary exposures, including drinking water, are included,
Consumption by seven different groups of infants and children, and
Consumption by individuals and groups with special food consumption patterns.

Even for those with little knowledge of pesticide risks, these assumptions are clearly preposterous. No national crop ever tested, much less all authorized crops, has ever contained the maximum permitted residue. Further, no pesticide has been used for 70 years. As newer, safer and more effective products are introduced, older products are removed and replace. Yet, S. 1074 requires EPA to establish tolerances based on these rigid and extreme assumptions and considerations. By making these assumptions and considerations mandatory, rather than merely permissible1 EPA is required to ignore reality.

To blunt criticism of its outrageous and unreasonable exposure calculations, S. 1074 contains a narrow exception to permit use of actual exposure data. Under the bill, EPA would be allowed to calculate dietary exposure on the basis of the percentage of the commodity actually treated only where it had reliable, statistically significant data on the percentage of food containing residues, and could show (1) that such percent is not likely to increase significantly in the subsequent five years, (2) that "the national distribution of such percent of such food...does not vary significantly from the distribution of the total amount of that food," and (3) that the aggregate risk from all pesticide residue on the food are negligible. This exception calls for data that does not exist—making it the "no-exception, exception." Given the wide disparity of pests, pesticide usage, and marketing of agricultural commodities, it would seem that few foods with residues are distributed evenly throughout the Nation. Showing that the percent treated would not increase in the next 5 years is an impossible prediction. These requirements would establish a virtually insurmountable evidentiary barrier.

INERT INGREDIENT TOLERANCE REQUIREMENTS

In practice, most inert ingredients are currently subject to tolerance exemptions, although EPA is reviewing inert ingredients which pose a toxicological concern and using data call-in procedures to determine conditions of safe use. By amending the definition of a pesticide chemical to include active and inert ingredients, S. 1074 will now require manufacturers to seek and obtain a tolerance or exemption for each inert ingredient. This is required, notwithstanding the fact that many of these products are currently either "generally recognized as safe," ("GRAS"), or have been granted exemptions. Nevertheless, under this bill EPA will be forced to review hundreds of inert ingredients, and possibly thousands of toxicity studies, when it could

and should be focusing its attention on new pesticide chemicals, re-registration, new active ingredients, or those with the most toxic inert ingredients.

To complicate mailers, EPA would be required to review all existing tolerances and exemptions, including inerts, within one year. And because the inerts would have to meet the negligible risk standard, new tolerances and/or exemptions would have to be established for virtually all inert ingredients. NACA believes that risks associated with inert ingredients need to be monitored. However, the scheme proposed by this bill would merely create chaos. The reevaluation of all inerts, without regard to how much could be present or as to toxicity, simply does not make sense.

PRACTICAL METHODS OF ANALYSIS

NACA strongly supports the proposition that FDA should have the necessary analytical tools to be able to quickly and accurately enforce the FFDCA. Currently, a tolerance will not be granted unless the petitioner submits a proposed method for analysis, and EPA has approved that method. This bill, however, insists that manufacturers develop only one type of analytical method. S. 1074 requires a "practical method of analysis," which is later defined as a multi-residue" method that can be performed on a routine basis as part of surveillance and compliance sampling. What the drafters apparently have failed to grasp is that some molecules and products are unique, and either do not lend themselves to such methods, or cannot be detected by such methods. In its zeal to consolidate residue monitoring, S. 1074 will instead hamstring FDA. Rather than simply mandate one type of test, NACA supports residue monitoring requirements where the agency would get the most—in terms of accuracy and quantity— for its money.

The only exception is that EPA would be authorized to permit a non-practical method of analysis only if a practical method was not available. This determination would have to be reevaluated every two years. This too, is a very limited exception. Multi-residue methods, when available and practical to use, can represent savings of time and effort in residue monitoring. However, this inflexible requirement will actually result in more expensive, less accurate and less efficient monitoring, because not all residues monitored in a multi-residue test are present in each food or crop tested. In such a case, the multi-residue method would be wasteful. EPA must be given the discretion to work with the petitioner to develop tests deemed appropriate by the Agency. Consultation with FDA would be only as needed.

S. 1074 simply misses the point on routine residue monitoring. In reality, not all pesticide chemical residues need to be routinely monitored. Even setting aside the administrative burden this bill would place on FDA, usage patterns of pesticides do not require multi-residue methods. It would be pointless to routinely monitor for substances where there is no reasonable expectation for residues and a tolerance is set at the sensitivity of the analytical method.

PHASED RISK REDUCTION

Currently, there is no statutory requirement under FFDCA that EPA review existing tolerances. However, under FIFRA, EPA is involved in a massive reevaluation of all registrations. That process includes a review of tolerances for food use pesticides.

Nevertheless, with the objective of expediting review of all existing tolerances to bring them in line with the new "negligible risk" standard, S. 1074 requires EPA to reevaluate existing data regarding the safety of each and every tolerance and exemption. Within 1 year, EPA must determine whether existing data is sufficient to make that determination. If EPA can't determine that the pesticide is "safe," its tolerance will be revoked. If EPA determines that it needs more data, it can then demand new safety studies. Under this scenario, EPA must have completed its review of all such tolerances within 7 years.

These proposed requirements are intended to be separate and distinct from the FIFRA re-registration process. Assuming that this redundant review is even necessary (which NACA does not believe), absolutely no attempt has been made to coordinate the two processes. NACA can see no reason to establish separate reevaluation requirements for pesticide tolerances and registrations. In fact, FIFRA re-registration contemplates review of each pesticide's tolerance. We believe that S. 1074 would interfere with FIFRA's re-registration, which is already behind schedule and overburdened by inadequate staff and insufficient funds. EPA has already testified in other hearings that they believe the deadlines established in FIFRA '88 cannot be met. Because this additional burden on EPA will only serve to exacerbate those problems, NACA opposes this provision in its entirety.

DATA CALL-IN

In view of the many complexities and potential for statutory conflicts that it introduces, it is a mystery why S. 1074 grants EPA data call-in authority under FFDCA. This is especially true since EPA already has broad existing authority to require the same data under FIFRA.

Scattered throughout the bill, but particularly in Section 408(c), as amended, the bill gives EPA sweeping power to require new health and safety data in support of both new and existing tolerances and exemptions. Similar to FIFRA, there are few limits on the type and quantity of testing requirements. Unlike FIFRA, however, any failure to submit the data on time (except for "extraordinary circumstances"), will result in automatic revocation of the tolerance or exemption. This penalty seems unreasonably harsh, and is unrelated to the severity of the omission.

Also, unlike FIFRA, a hearing on the merits of the data call-in and deadlines would be available only after the tolerance or exemption is revoked. Since the cost of data development and potential for legitimate controversy are so great, S. 1074 goes far beyond what is needed, or indeed, reasonable, in granting EPA both the authority to require data, and the procedural hammer to argue the equity and lawfulness of its demand after-the-fact.

DATA CONFIDENTIALITY

S. 1074 utterly fails to protect confidential information from public disclosure, both before and after EPA acts on a tolerance or exemption. While purportedly providing "limited public access," even a cursory reading of the "Disclosure" paragraph reveals that the confidentiality provisions are more accurately described as "limited confidential treatment."

Currently, FFDCA prohibits public disclosure of data supporting tolerances until after the agency has taken final action on a petition. This is for good reason. Manufacturers spend millions of dollars developing products, conducting in-house safety tests, and conducting EPA required safety and efficacy testing. Until this data becomes a product and receives a patent, or until the manufacturer becomes entitled to data compensation under FIFRA, this information is arguably the most sensitive information maintained by the manufacturer.

In practice, data supporting both tolerance and registration petitions are submitted under FIFRA. FIFRA limits public disclosure, at any time, of certain confidential business information, bars disclosure of registration data to competitors, and provides for use exclusivity and gives compensation for certain data. Current practice adequately protects the manufacturer, and provides EPA with all of the information it needs to conduct its review of the product.

S. 1074 renders current protection under FIFRA meaningless, and would make it impossible for manufacturers to keep confidential trade secrets and business information out of the public domain. Under this exception-riddled provision, data submitted in support of a petition would be entitled to confidential treatment for only 45 days—until the Administrator publishes the initial Notice that a petition to establish a tolerance has been filed. Thereafter, the Administrator is required to publish a summary of the safety data submitted in support of the petition. In addition, under Section 408(g), the Administrator shall provide . . "public access to health and safety data that are submitted or cited in support of such petition." Of course, anyone requesting that data must attest that they are not a competitor. However, it does not take much foresight to envision the following scenario. A person wishes to contest the data supporting a petition, and he files a lawsuit seeking to enjoin issuance of a regulation establishing a tolerance. In the process, the information in the petition becomes public. And while the person seeking access to the data prior to EPA action must state that he will not "intentionally or recklessly" violate that subsection, there is no protection should that person ever negligently disclose confidential information. Therefore, the affirmation is meaningless; this type of protection is no protection.

Furthermore, data in support of a petition may be released before agency action on the petition to "either House of Congress or any committee or subcommittee thereof to the extent of matter within the jurisdiction of the committee or subcommittee." Mr. Chairman, we can imagine absolutely no justification for this intrusion into the exclusive decision making domain of an agency prior to agency action. Indeed, this provision does not even limit the information to members of the committee or subcommittee. Presumably, staff members, who are not bound by the confidentiality provisions of proposed Section 408(g)2, would also have access to this information. This provision is understandably unacceptable.

On a more pragmatic level, disclosure of such data (whether before or after final agency action on the petition), undercuts both the data compensation and confidentiality provisions of FIFRA. Millions of dollars in research and development depend on the protection provided under FIFRA. Without the guarantee of exclusive use, companies would not risk the costs associated with the development of any new product. The effect on safer pesticides, minor use, and eventually all products, would be devastating.

PROCEDURES FOR ESTABLISHING OR MODIFYING A TOLERANCE

The proposed requirements of S. 1074 for establishing a tolerance are unworkable. FFDCA tolerance-setting will now be subject to the imprecision, delay and frustration known as "notice and comment rulemaking." Such rulemaking typically suffers from lack of agency accountability, indifferent rulemaking records, and arbitrary results. Taken in combination with (1) provisions for public assess to supporting data, (2) elimination of the input of the NAS scientific advisory committee, and (3) the rights of persons with no direct interest to submit comments and participate in the proceeding, the proposed procedure will quickly cause the administrative wheels to grind to a halt. Even those petitions which would be entitled to priority under the bill are given no procedural advantage. Presumably, the drafters were aware of the certain delays, as they have given the agency fully three times as long to make its decision establishing a tolerance. Manufacturers have invested heavily in research and development for new products. To subject them to such long delays gives them no incentive to bring new products to market. Understandably, these provisions are also unacceptable.

The provisions of S. 1074 for revocation/modification of a tolerance suffer the same procedural flaws. Additional problems involve the right of any citizen to petition to have a tolerance revoked, revocation for failure to pay maintenance fees, and the revocation of existing residue tolerances without adequate opportunity to defend their safety.

JUDICIAL REVIEW

S. 1074 contains major deficiencies in its judicial review provisions. Making objections and requesting a hearing would not be required as a prerequisite to obtaining judicial review of action on a petition. In fact, a person whose petition was denied would not even be entitled to file objections or obtain an evidentiary hearing before the denial becomes final. Additionally, the right to obtain judicial review is substantially enlarged by allowing any person who may be adversely effected to seek judicial review. This, in conjunction with new provisions providing attorney and expert witness fees (which may be substantial in such technical cases) will no doubt encourage frivolous, time consuming and expensive litigation.

However, the most unusual provision regarding judicial review is the inexplicable shift of the initial burden of proof, typically on the petitioner, to the agency. This "guilty until proven innocent" approach is fraught with several practical, and potentially legal, pitfalls. For example, the agency may well find itself so inundated with challenges from disinterested third parties that it will be unable to carry out its administrative functions in a timely manner. Placing the initial burden of proof to justify its action only encourages litigation. A petitioner is able to rely on a largely undeveloped administrative record, because there is no provision for an evidentiary hearing prior to appeal. In addition, the person who originally sought the petition is held captive to a cumbersome judicial process, and products which may have been a tremendous benefit to production agriculture will be lost. At the very least, the cost of litigation for the agency in terms of time, money and energy will be substantial.

It is difficult to see why the issuance, amendment or revocation of tolerances should be judicially challengeable only after both formal and informal rulemaking, while petition denials could be the subject to direct judicial review, without opportunity to develop or supplement the administrative record, or without consideration of the views of other interested persons under either formal or informal rulemaking.

PIPELINE PROVISION

It is true that FFDCA currently does not contain an express pipeline provision allowing treated crops to "move through the system" if a tolerance is modified or revoked. However, any potential problem in this area is solved by current EPA and

FDA authority to delay action, or to utilize "action levels" to trigger discretionary enforcement action.

Under S. 1074, however, EPA allows a revoked tolerance to remain in effect for raw agricultural commodities and processed foods which, on the date of publication of the regulation, contain pesticide residues in compliance with the original tolerance. This provision does nothing to protect the majority of existing legally treated food—including growing but unharvested crops. In addition, it is not clear whether the exemption would extend to processed food that is made the date of the regulation from raw agricultural commodities which contained legal residues prior to the date of the regulation.

This provision is wholly inadequate to protect this country's farmers who legally apply products registered with EPA. On an even more basic level, the bill fails to coordinate with similar pipeline provisions of FIFRA. FIFRA authorizes EPA, upon cancellation of a product1 and within EPA discretion, to allow pesticides to be used until supplies are exhausted, on the assumption that limited use over the country is environmentally preferable to concentration of the product in stopping its use, and ordering its disposal. S. 1074 counteracts this sound environmental policy by effectively prohibiting use of all unapplied pesticides in storage and inventory.

USER FEES

Current FFDCA provisions require those seeking to establish or lower a tolerance to pay a fee, typically ranging from $10,000 to modify an existing tolerance, to $50,000 to establish a new tolerance. S. 1074 will not only continue to assess these same fees, but also authorizes(1) payment of an annual maintenance fee, and (2) payment of a fee sufficient to cover the costs associated with reevaluation of all existing tolerances. This amounts to two new fees. If history is any indication, S. 1074 may well be the death knell for minor use products.

As a result of the additional fees levied on manufacturers through the FIFRA '88 re-registration process, hundreds of product registrations have been and will continue to be dropped because the manufacturers are unable to afford to keep them. Included in the lost registrations will be safer pesticides and minor use products. At best, the additional fees required here will increase the cost of the product to the manufactures, who will be forced to pass the increase on to the producer, who will pass them on to the consumer. Higher food prices may not sound an alarm for the well healed who regulate and advocate. However, for the vast majority of Americans, higher food prices are not a realistic option when the result is food no safer than it was before. Of course, the other possibility is to lose more minor use products.

CONCLUSION

Again, Mr. Chairman, I wish to thank you and the members of this Committee for the opportunity to present these remarks on S. 1074.

The CHAIRMAN. I appreciate all of the statements and comments, and we may submit some additional written questions to all of you.

I have been impressed with all of the panelists today indicating their desire to work with the committee for a safer food supply. I think there are varying and different opinions about the nature of the process and procedures which are being followed and whether existing laws are adequate in terms of continuing to provide safety in some areas and permitting very careful oversight which I think is necessary in a number of other areas, particularly with regard to the children in our society.

We are going to take some action. There are dynamic forces out of play across this country, and families will continue to be concerned about the safety of the food supply. The question is are we going to play a type of Russian roulette with certain areas of our food supply, or are we going to proceed rationally. The States are going to move ahead. Anyone who doesn't believe that hasn't been traveling around the country. It is part of the whole political phenomenon over the last 10 years. They've said if the Federal Gov-

ernment won't do it—let the States do it. Well, the States are doing it in a variety of different ways all over this country. They may have defeated a proposal out in California, but there is an inevitability about it.

So if we are not able to bring together in a responsible, reasonable and rational way the various interest groups, I think there is going to be confusion and disruption, and we will provide a real disservice to the families in this country. And I think there is an increasing awareness of this.

I mentioned at the outset of this hearing my appreciation for my colleague Senator Hatch's willingness to work with us. We worked with the administration and made important progress in the last session. We weren't able to really achieve all the things I think all of us would have liked to do, but we heard spokesmen and women indicating different interests in this issue, and we will be listening to you and will be calling on you as we move this process forward. But the process will be moving forward, and I think the earlier, the better, as far as I am concerned.

I want to thank all of you very much for your patience this morning and for your comments. All the statements will be put in the record in their entirety, and we'll permit a reasonable number of questions by committee members if they so desire to be directed toward any of the witness.

[Additional statements and material submitted for the record follows:]

PREPARED STATEMENT OF THE CHEMICAL PRODUCERS AND DISTRIBUTORS ASSOCIATION

I am, Gregory J. Duerksen, Chairman of the Food Safety Committee of the Chemical Producers & Distributors Association. The CPDA is a voluntary, non-profit membership association consisting of some 75 companies engaged in the manufacture, formulation, and distribution and sale of products used on food, feed, and fiber crops, lawn, garden, and turf care, and public health pest control. I an, also Vice President, Marketing and Development, for Terra International, Inc., one of the Nation's largest crop production product and service marketers.

The CPDA sees several positive attributes in S. 1074, but we also have many serious concerns. We cannot support the bill as currently written, but believe that with amendments the bill can be significantly improved. In fact, redefining the issues addressed in the bill could lead to legislation that would benefit consumers, environmentalists, farmers, and pesticide manufacturers.

Let's look first at redefining the issue, then attributes of S. 1074, and finally concerns regarding this bill.

REDEFINING THE ISSUE

As a father, I am acutely concerned about my kids' health and the safety of the food they eat. As an environmentalist, I believe we need to continue cleaning up our environment so people and wildlife will be able to enjoy it in ever-better condition for generations to come. And as a part of the farm input industry, the CPDA's and my company's responsibility is to help farmers produce a safe, abundant, affordable, competitive food supply for the United States and world marketplace. Contrary to popular opinion, these goals are not mutually exclusive; rather, they are complementary. But the policies and actions to achieve these goals must be thought through and implemented carefully. Thus, while we applaud several of the ideals in S. 1074, we are greatly disturbed by the sole focus of S. 1074 on pesticide residues.

As we consider pesticides and food safety, we must step back and ask ourselves what the real issue is and what our real goal is. Is the issue pesticide residues? Is it safety, and nothing else? Or is the real issue and goal the total health and nutrition of United States and world consumers? We believe it is the latter.

S. 1074 addresses only the risks of using pesticides, but excludes consideration of any benefits. This is shortsighted, as risks and benefits must be weighed. Moreover,

comparative risks must be weighed. This simply says that all options have risks as well as rewards, and these must be balanced. For example, when I took try kids to the pediatrician for their whooping cough immunization shots, I knew that from the vaccine there was a 1-in-10,000 risk they would contract whooping cough, which can be fatal. However, this "sin of commission" was vastly less than the risk of disease and death. With the same logic, most cities chlorinate their water supply, knowing that the cancer risk from chlorine—a known carcinogen—is less than the public health risk of unchecked microbes in drinking water. We all use x-rays to diagnose various illnesses, but an overdose of X-rays is bad for our health.

Likewise, using pesticides has risk, and not using pesticides has risk. One of America's most prominent entomologists noted that "I would rather go into a supermarket and, say, find a tenth of a part per million of a certain pesticide on apples or lettuce than to find a cockroach that is carrying 40 or 50 disease organisms on his foot crawling over the lettuce. " There is a very good reason we use fungicides on fruits and vegetables: fungus residues can be infinitely more harmful than pesticide residues. And very importantly, the risk of not using pesticides is that food costs would rise dramatically. In fact, a recent estimate by GRC Economics predicts a 45, rise in food costs if synthetic pesticides and fertilizers were banned. This would have a disastrous effect on the nutrition and health of the 30 million Americans who already spend 60% of their income on food. And one of America's most significant environmental and conservation advances of recent decades would be reversed because soil erosion would rise dramatically as farmers substitute more cultivation for pesticides.

Food must be affordable and abundant and safe to truly benefit the United States and world consumer. One of the keys to economic growth, and the resultant improvements in quality and quantity of life, is that food costs as a proportion of income have been continually dropping. In 1950, food and beverage costs were 19% of America's GNP, and by 1990 they dropped to 11. On a $5.5 trillion GNP, this savings is worth over $400 billion annually. That's nearly $600 per year per person, and enough to pay for 20 Clean Air bills. These savings are at least partially attributable to productivity improvements from pesticides.

Why is this important? The National Research Council says that nutrition is the number one food-related public health issue in the United States. Quite simply, affordable food makes better nutrition possible for the people who most need better nutrition. Conversely, well-intentioned but incomplete pesticide. residue legislation that leads to higher food costs forces a most cruel and pernicious choice on those who can afford it the least. Specifically, "Can my family afford fresh fruits and vegetables? Can my family afford meat?" I speak from experience. Growing up in rural South Dakota, in winter my parents often had to ask whether they could afford fresh fruits and vegetables for their kids. Often the answer was "no." No family should have to make that cruel choice. Properly crafted, S. 1074 could help ensure that choice must never be made.

Consumers in the United States are only part of the issue. One quarter of our agricultural production is exported, and much of that to developing countries. If legislation leads to higher commodity prices, the poorest will suffer. Our agricultural competitiveness will also be undermined, and consequently our balance of trade will suffer. In 1950, agricultural exports were only $3 billion, but in 1969 they were $40 billion. Loss of these exports would adversely affect our entire economy.

We could spend billions of dollars on higher food prices, wreak havoc on the economy and labor force, and at best have no safer food supply. That is because, thanks to our current system, pesticide residues are irrelevant in their contribution of carcinogens to the daily diet. Several prominent scientists have estimated that we consume roughly 1,500,000 micrograms daily of naturally-occurring carcinogens, while the Food & Drug Administration estimates that the average American consumes 150 micrograms of pesticide residues daily, of which 45 micrograms are possibly carcinogenic. In comparison, University of California at Berkeley researchers estimate that one large potato contains 15,000 micrograms of natural carcinogens (various alkaloids), one cola contains 2,000 micrograms of the natural carcinogen formaldehyde, and even a slice of bread has 185 micrograms of the same substance.

This does not mean we should quit eating potatoes or bread, but simply points out the old toxicologists' maxim that "the dose makes the poison." For example, salt is essential to life, but the amount you can hold in your hands can kill you. Vitamin A is essential, but at high enough doses it is a reproductive toxin. Now I do not mean to imply that pesticides are essential to life, but am simply trying to point out that infinitesimal amounts are irrelevant.

ATTRIBUTES OF S. 1674

The single most important attribute of this bill is that it does indeed recognize that infinitesimal amounts of pesticide residues are irrelevant, and would replace the Delaney Clause with the concept of negligible risk for non-threshold pesticides. This is a very important acknowledgement of our ever-increasing ability to detect miniscule quantities of substances.

And regarding what level of negligible risk is acceptable, in concept we have no objection to a target of a one-in-a-million standard, but in practice our regulators must not be tied to a specific number, because they must be allowed to look at comparative risks (The whooping cough vaccine situation cited earlier is a perfect example.) and adjust to rapid scientific advances in risk assessment.

Government agencies should not be placed in a numerical straitjacket, but should be given the flexibility to modify their views of acceptable risks based on scientific advances. This flexibility is essential because of changing technology, our changing ability to assess and understand comparative risks and benefits, and the need to understand what is the appropriate safety factor in each situation. Many argue that, in the case of pesticides, there must be no more than a one-in-a-million risk. Just where does this number come from? We suspect it simply sounds "safe." And it may in fact be the right level of safety. But sometimes not.

This concept of negligible risk was summarized eloquently in 1989 testimony before the House Agriculture DORFA subcommittee by Dr. Charles Benbrook, then Executive Director of the National Academy of Science's Board of Agriculture. He concluded that there were "valid arguments both for and against specifying a quantitative benchmark in the definition of negligible risk." Benbrook concluded, that "... In the end, the committee was persuaded that quantitative risk assessment methods, and the science underlying estimates of carcinogenic risks, were too fragile and changeable to either assert that risks below a certain level are truly 'negligible', or that risks above the 'negligible' level indeed pose a significant risk of cancer in man." It is important that these scientific evaluations be made only on a case-by-case basis after a complete review of the toxicological data base. We believe it is prudent not to set definitive numerical values for negligible risk within any statutory provision.

In addition, any negligible risk standard requires fact-based risk assessment. Unfortunately, S. 1074 dictates an onerous worst-case scenario that barely qualifies as theoretically possible: pesticides must be assumed to be used on 100 percent of the crops and acres labelled, residues are at the maximum allowed, and consumption of residues occurs at the maximum for 70 years. The chance of any of these worst-case assumptions occurring is extremely remote, so total residue exposures are vastly overstated.

We propose a two-point approach to get a realistic handle on pesticide residue exposure: pesticide record-keeping, and a market basket approach to residue monitoring. As a result of the 1990 farm bill, farmers will already be required to keep records of restricted-use pesticide applications. This process could be expanded to all pesticides. And the FDA already does limited testing of foods to look for pesticide residues, which could be broadened to provide a statistically-significant overview of pesticide residue exposure in the foods we actually eat. The result of this two-point approach is that we would find some pesticides where the risk is greater than we had assumed, and others where it would be less, and we could respond accordingly.

With this more realistic risk assessment, we then pave the way for introduction of safer, more cost-effective pesticides that serve the total health improvement goal described earlier.

A "no observable effect level" (NOEL) is proposed for determining negligible risk for threshold pesticides. Again, we applaud the concept of dividing the NOEL by 100 to establish an Acceptable Daily Intake (ADI), but don't believe we should lock the EPA into a rigid number, as we need flexibility to respond to our changing knowledge base.

Another attribute of S. 1074 is that it points out the need to evaluate the exposure of pesticide residues to population subgroups. However, the EPA needs the flexibility to change the population subgroups evaluated as new information emerges or specific situations arise, and should not be locked in to a rigid list of subgroups.

While we are establishing the negligible risk and risk assessment provisions, we must also establish national uniform tolerances and procedures. The States are simply not prepared to adequately set up fact-based standards and then review them. Consequently, leaving them to set their own standards would make S. 1074's noble efforts irrelevant in the wake of decisions based on emotion, conjecture, and

misrepresentation. We believe the EPA should set tough standards, taking into account specific local situations, but then allow these standards to be uniform, thus balancing the need to protect our environment and allow cost-effective product development and testing. In addition, national uniform tolerances ensure that interstate and international barriers to trade are kept to a minimum.

We also approve of most of the provisions and process steps outlined for petitions and actions by the EPA Administrator. However, we are very concerned about the judicial review sections. First, there is no objection or hearing step before a denial of a tolerance becomes final, and the only option is judicial review. And the judicial review option is opened to any person who may be adversely affected, and specifically including those who do not have an economic interest. This, plus provisions which allow the recovery of attorney and expert witness fees, is a loud invitation to frivolous lawsuits. The problem is compounded by the placing of the burden of proof on the EPA rather than the petitioner, even to the point of requiring the court to determine that the defined data are adequate to keep the tolerance. This is quite simply a "guilty until proven innocent" approach.

CONCERNS WITH S. 1074

This bill has a number of concerns that we believe can be addressed and corrected.

Under the definitions, for example, negligible risk is defined as "reasonably certain to cause no harm to human health," and residue tolerances must be established at a level which "will not cause or contribute to any known or anticipated harm to human health." These could easily be interpreted as zero-risk standards.

Pesticides are redefined to include inerts, which means manufacturers would be required to get a tolerance or exemption for each inert, even though many are on the GRAS list. This is simply a waste of researcher and EPA resources that could be better spent trying to develop and approve newer, safer pesticides or reregister older pesticides. We suggest establishing tolerances only for those inerts of toxicological concern. In fact, the EPA is already reviewing this category through data call-in activities.

A proverbial Pandora's box of new taxation is opened in the provisions that authorize new fees to do this work. First, we don't think new fees are needed, because if any of the activities envisioned in this bill are priorities, the EPA can do them and let lower priorities wait. Moreover, if new fees are indeed necessary, they must have a narrowly-defined purpose and the EPA must have tight performance standards to ensure the money is not wasted.

Lastly, the proposed evaluation of existing tolerances and the accompanying timetable is an impossible task. Tens of thousands of tolerances will have to be reproven. The Administrator needs much more flexibility in this entire area to set priorities. More fundamentally, this task is already being accomplished through the reregistration process.

We have many other procedures and process concerns, but the above issues are the most important.

CONCLUSION

In summary, S. 1074 needs an integrated, balanced approach to pesticide use, food safety, and the broader and more important issue of the total health and nutrition of American and world consumers. We need an approach that understands the alternatives of "sins of omission" and "sins of comission". We need to look at real data (i.e., market basket approach) and real risks, not ivory-tower chemophobe models. We welcome the opportunity to work with you on S. 1074 so it truly advances the long-term health and environment of the United States and the world.

JOINT PREPARED STATEMENT OF THE NATIONAL CORN GROWERS ASSOCIATION, THE AMERICAN SOYBEAN ASSOCIATION, THE NATIONAL ASSOCIATION OF WHEAT GROWERS, THE NATIONAL BARLEY GROWERS ASSOCIATION AND THE NATIONAL COTTON COUNCIL

Chairman Kennedy, I am very pleased to address your committee on behalf of the National Corn Growers Association, the American Soybean Association, the National Association of Wheat Growers, the National Barley Growers Association and the National Cotton Council. Our groups have forged a close working relationship on many environmental and conservation issues that has been beneficial for our members and, we hope, for congressional debates on these topics.

The issue that initially brought us together involved the wholesomeness of our Nation's food supply and it is thus with a sense of satisfaction that I address food safety here. Our farmers turn out the most abundant array of high-quality food and fiber available on earth. That abundance also allows American consumers to pay a smaller percentage of their income for food than people in any other country in the world. Obviously, our Nation's generous resources of land, water and climate deserve much credit for the bounty we harvest each year. I'd even like to think farmers' knowledge of the land has a little to do with it. But it is undeniable the use of pesticides and other chemical inputs plays a major role in helping farmers produce the food supply Americans take for granted.

We know it is not just the quantity of food we produce that is important. We also know we must maintain the high quality of our agricultural products. For the most part, the Federal regulatory system has worked well to ensure our food supply is safe, and where it has not worked well enough the problem has frequently been a lack of agency resources. Our organizations realize that skepticism about our ability to deliver safe food is cause for concern and we reiterate our commitment to work with you and other government officials to maintain public confidence in our food supply.

Mr. Chairman, you and your House colleague, Rep. Henry Waxman, have been at the fore of the food safety debate in Congress, and by introducing S. 1074 you are again proposing major revisions to our nation's regulation of pesticide use. While your bill would improve current law in several respects, it also has numerous provisions that would make current law unworkable, seriously harm agriculture and compromise our food supply.

We submit that the Food Safety Assurance Act, introduced by several members of the House Agriculture Committee in the last Congress, would bolster consumer confidence through a much more balanced approach toward improving Federal regulation of pesticide use.

At this juncture, I'd like to outline our positions on a wide range of pesticide regulation issues, including observations on some of your proposals. With respect to the cancellation provisions of the Federal Insecticide, Fungicide and Rodenticide Act, the Environmental Protection Agency is now empowered to cancel a pesticide registration if information shows the chemical presents an unreasonable risk to human health or the environment. But the cancellation process can be unnecessarily time-consuming and expensive and rarely reduces controversies about either a pesticide's continued use or EPA's ability to regulate pesticides responsibly. Legislation is needed to streamline the process while retaining provisions for public participation that would contribute to valid scientific assessments of pesticide products.

If such improvements to the FIFRA cancellation process are made, changes in the current suspension authority would be inappropriate. EPA has substantial authority to temporarily suspend a registration pending permanent cancellation proceedings if the pesticide poses an "imminent hazard." Changes in either that.hazard threshold or suspension procedures would curtail the public's ability to participate in regulatory decisions and could result in the removal of essential pesticides from the marketplace.

While we feel current suspension authority is adequate, we agree with you that changes are needed in the outmoded "zero risk" Delaney Clause of the Federal Food, Drug and Cosmetic Act, which regulates pesticide residues on food. We oppose your proposal of a rigid numerical risk standard, however. A narrative definition of "negligible" risk more realistically assesses risks at a time when testing procedures now can measure truly minuscule residues—down to the part-per-trillion or part-per- quadrillion. We also find fault with your bill's rigid formulae for risk calculation, its imposition of arbitrary quantitative standards, use of theoretical assumptions on exposure that are known to be false, and preclusion of the use of biological data on mechanism of action. Instead, we feel all scientific information and known factual data should be used in determining negligible risk.

Benefits of pesticides should also continue to play a role in regulation of pesticide use and allowable residues, and your bill's failure to do so is a major cause of concern for our groups. It is only logical to give weight to a pesticide's contribution to improved public health and welfare through availability of foods that are nutritious, varied, economical and safe, as well as its role in maintaining a robust agricultural economy.

The vitality of the farm sector is threatened by a patchwork of different State-set tolerances. for acceptable pesticide residues that could interrupt food production and distribution. Unfortunately, your proposal fails to address the need for uniform tolerances for pesticides that meet the comprehensive data requirements of current EPA regulations. Any new legislation should provide that, with limited exceptions,

tolerances established by EPA for pesticides that have been reregistered under updated FIFRA standards be applicable nationwide.

Speaking of the reregistration process, amendments are needed to ensure pesticide registrations and supporting data are current. Pesticide registrants should periodically submit scientific data and other information sufficient for EPA to determine whether existing registrations are proper. This reregistration provision should establish benchmarks for data submission and EPA review.

Consultation and coordination within the Federal Government on food and pesticide regulations also needs improvement. Given the linkage between pesticide use, agricultural production and food safety, regular consultation is needed between EPA, the Department of Agriculture and the Food and Drug Administration. Our groups have been encouraged in recent weeks, however, to hear officials from EPA and USDA praise each other for cooperating in a variety of areas. We hope that spirit of coordination will flourish in the months ahead.

Finally, looking beyond our borders, current U.S. regulation of pesticide exports should be amended to guarantee both pesticide use abroad and pesticide residues on imported food do not endanger human health. The amount of FDA sampling of food imports needs to be increased and residue monitoring improved. In addition, exports of pesticides that have been cancelled for human health reasons should be prohibited.

Mr. Chairman, as was the case when it began 2 years ago, the issues of the food safety debate continue to be complex and, frequently, emotional. But just as our organizations have worked together to hammer out common, realistic positions, we hope you and other Members of Congress can reach consensus on proposals that will balance legitimate science-based concerns about pesticide use with the enormous benefits they allow farmers to give our society. Thank you for allowing me to pass along the views of our Nation's barley, corn, cotton, soybean and wheat farmers.

PREPARED STATEMENT OF LARRY THOMSEN PRESIDENT, NATIONAL AGRICHEMICAL RETAILERS ASSOCIATION

Mr. Chairman and members of the subcommittee, on behalf of the over 1,500 retail dealer members of the National AgriChemical Retailers Association (NARA) who market pesticides directly to farmers nationwide, I would like to thank you for giving our segment of the pesticide industry an opportunity to submit a written statement regarding S. 1074, the "Safety of Pesticides in Food Act of 1991."

The members of NARA do not support S. 1074 because the bill would be detrimental to the production agriculture industry in the United States and the general economy of our agriculturally dependent rural communities. Many of the small agribusinesses that are owned and operated by the members I work for, including our cooperative, would be economically impacted by this bill. By forcing safe pesticides off of the market due to its overly stringent standards and increasing the cost of getting much needed crop protection chemicals to market, the bill will negatively affect agricultural production. Since many of the technical aspects of this bill have been covered by industry experts on Food Safety, I would like to focus on the potential "real world" effects S. 1074 will have on agriculture, and then discuss our specific objections to the bill.

POTENTIAL REAL WORLD EFFECTS ON AGRICULTURE

Nature makes it difficult for farmers to produce crops in the face of hundreds of weed species, 1,500 plant diseases, more than 1 million insect species, and at least 1,000 species of nematodes. However, with the development of crop protection chemicals, one U.S. farmer now feeds over 120 people around the globe and has increased food and fiber productivity more than 230 percent since 1940.

With the restrictions that would be imposed by S. 1074, products that are now considered safe and have contributed to our abundant food supply would be taken off of the market due to overly restrictive risk standards and other stringent requirements. In addition, S. 1074 may force many domestic crop protection chemical manufacturers with a global market to move their production facilities overseas. In turn, American farmers who depend on products developed and produced in the United States would be forced to depend on products produced overseas. Although some would dispute this statement as industry rhetoric, I can give you an example of a situation that currently exists in the crop protection chemical business to support my claim. This example makes a comparison between the current situation

with regard to minor-use pesticides and the potential effect S. 1074 could have on our farm community.

Today, as a result of the reregistration requirements contained in the amendments to the Federal Insecticide, Fungicide and Rodenticide Act in 1988, many minor use products used in the fruit and vegetable industry will be lost, wreaking havoc on the consumer market. S. 1074 will only enhance these problems by requiring further testing requirements and overly conservative risk standards, placing more of the over 2,000 minor use pesticides currently in jeopardy of losing their registration out of the market. Testing requirements to support registration include toxicological studies that cost several million dollars. When comparing this multi-million dollar cost with the $10,000 gross revenue that a minor use product brings in, it is easy to predict that the registration for that product, no matter how important to the U.S. farm community, will be dropped. The ripple down effect of lost minor-use products will result in lost major use products, causing a greater reliance on foreign produced food.

By carefully assessing the requirements that S. 1074 proposes and reviewing our current experiences with minor use products, it is safe to assume that many products will be dropped from the market at great cost to the American consumer and agricultural industry. The "real world" effects must be considered before the bill is passed.

SPECIFIC OBJECTIONS TO THE BILL

NARA is opposed to the passage of S. 1074 for the following specific reasons.

1. Eliminates the consideration of the benefits of pesticides to the public;
2. Establishes overly rigid numerical risk standards;
3. Does not address current problems between Federal, State, and local law; and
4. Proposes overly conservative exposure assumptions.

ELIMINATION OF BENEFITS CONSIDERATION

S. 1074 proposes to eliminate the consideration of benefits when regulators set tolerances for a particular pesticide on all food. NARA strongly opposes this particular aspect of the bill.

Failure to consider the benefits of a pesticide, which may have minimal impact on human health but enormous benefits in food production, is not sound public policy. Studies have shown that the economic and social cost of banning the use of certain pesticides is high. According to a study conducted by the United States Department of Agriculture's Economic Research Service, banning Alachlor and Methachlor in corn and soybean production would cost $2.2 billion per year, and banning Triazines would result in losses of $3.4 billion per year. In our view, the elimination of benefit analysis may increase the likelihood that certain safe and beneficial pesticides, like those mentioned above, could be taken off the market, in light of the more stringent negligible risk standard that S. 1074 proposes.

Congress must not only consider the benefits that pesticides provide in food production, they must also weigh the economic welfare of rural, agriculturally dependent communities. Just like a drought, flood or other natural disaster, pests can cause total economic ruin for agricultural producers in a very short period of time. Without the insurance that pesticides provide, farmers go unprotected, leaving in their wake the small businesses and communities they support.

ESTABLISHMENT OF RIGID NUMERICAL NEGLIGIBLE RISK STANDARD

Although our members support the establishment of one negligible risk standard in regulating pesticide residues in all food, S. 1074 extends beyond what is necessary and prudent by proposing a rigid one-in-a-million standard for non-threshold risk and a 100 fold standard for threshold risk. Our members are confused as to why the authors of this legislation continue to propose the establishment of a concrete risk standard when the overwhelming consensus among the scientific community rejects this proposal.

Why is the establishment of a set risk standard opposed by scientists? First, the science of risk assessment is continually changing, with new and more accurate assessment procedures being developed. A set risk number would become obsolete and unworkable as science changes. Second, each chemical is unique, presenting a different set of variables which must be considered when evaluating risk. A set risk number unfairly establishes criteria that may or may not be met by a particular

pesticide, jeopardizing its registration based on inaccurate analysis and inflexible criterion. From a small agribusiness perspective, the establishment of a concrete risk number could result in unfair removal of many products from the market.

In addition, the bill calls for a special risk standard for the first 5 years after a person is exposed. This special standard was established to address concerns over the potential exposure of children to pesticide residues. We feel that this proposal is premature in light of the forthcoming National Academy of Sciences (NAS) report on pesticides in the diets of children. Congress should wait for the results of this study before it establishes overly conservative risk numbers for children.

UNIFORM TOLERANCE PROVISION

Only exacerbated by the recent U.S. Supreme Court decision which gives local jurisdictions the power to write their own pesticide laws, this bill fails to address the interface between existing Federal and State regulation of food. Currently, States are setting lower tolerances for pesticide residues in food than those established by the U.S. Environmental Protection Agency (EPA). This situation, where distribution and marketing systems must cope with a patchwork of inconsistent State-by-State requirements, creates the potential for considerable consumer confusion and substantial disruption of interstate commerce in food production.

In light of the recent Supreme Court decision, Congress must act soon, allowing already stringent Federal standards to preempt State and local standards. Variations by States and local jurisdictions only hinder trade, thereby diminishing the United States' competitiveness on the world agricultural market.

CONSERVATIVE EXPOSURE ASSUMPTIONS

S. 1074 proposes that the EPA make pesticide exposure assumptions which clearly are unreasonable and would hurt the agricultural industry. For example, S. 1074, among its many other overly conservative requirements, requires the EPA to assume that residues occur in 100 percent of commodities for which treatment is legal, and that all crops have the maximum permitted residue. From personal experience, I can tell you that the assumption that the same residue occurs in 100 percent of commodities for which treatment is legal, never happens.

The farm cooperative that I work for in Iowa markets many different pesticides used on corn for the same agronomic purpose. Taking this fact into consideration, forcing the EPA to assume that certain residues from particular products are found on all corn would greatly overestimate the actual residue that exist. Simply stated, the very conservative exposure assumptions contained in S. 1074 would detrimentally affect U.S. agriculture. Neither the public nor the food producing industry is served by assuming worst case scenarios when actual use data is available to provide more realistic and accurate information. Reality must be an integral part of establishing food safety standards.

CONCLUSION

S. 1074 goes far beyond what will be workable for the agricultural community and promises to exacerbate our current problems with minor use pesticides and reregistration efforts. Because the United States produces the safest food in the world, I think that the goal of Congress, through S. 1074, to predict our citizens' health by unreasonably governing pesticide use may only diminish our profitable agricultural industry without increasing our country's health standards.

NATIONAL AGRICHEMICAL RETAILERS ASSOCIATION
Washington, D.C. 20005, July 11, 1991

The Honorable EDWARD KENNEDY,
U.S. Senate,
Washington, DC 20510

DEAR SENATOR KENNEDY: Enclosed is a copy of the written statement of Larry Thomsen, president of the National AgriChemical Retailers Association (NARA), opposing S. 1074, the "Safety of Pesticides in Food Act of 1991." NARA represents over 1,400 retail AgriChemical dealers across the United States.

Due to the delayed announcement of the hearing by the Senate Labor and Human Resources Committee, Mr. Thomsen was unable to present an oral statement. How-

ever, his written statement was made part of the Record. Below, I would like to review NARA's problems with the bill.

First, the bill contains a rigid formula for risk calculation, imposes arbitrary quantitative standards, requires the use of theoretical assumptions on exposure that are known to be false, and prevents the use of biological data on mechanism of action. These problems will result in perfectly safe products being taken off the market.

Second, the bill fails to address the need for uniform tolerances for pesticides that meet the comprehensive data requirements of current EPA regulations. In light of the recent Supreme Court Decision granting local jurisdictions the power to make their own pesticides laws, Congress needs to take action immediately to prevent a national agricultural catastrophe resulting from thousands of unworkable laws.

Third, the bill fails to provide for consideration of health, nutrition, agriculture, and other consumer benefits in determining whether a tolerance should be permitted for a pesticide in food products. This proposition is completely unrealistic. Pesticides unquestionably provide tremendous benefits to society.

Fourth, the bill would increase the loss of minor use pesticides and would further discourage the development of pesticides for minor use. In fact, the over 2,000 minor use registrations currently in jeopardy would, in most cases, be taken off the market immediately.

Thank you for taking into consideration our views on S. 1074. I look forward to hearing from you regarding your position on the bill.

Sincerely,

CHRIS MYRICK, DIRECTOR
Legislative/Regulatory Affairs

PREPARED STATEMENT OF THE NATIONAL COUNCIL OF FARMER COOPERATIVES

Mr. Chairman and members of the committee, the National Council of Farmer Cooperatives (National Council) is pleased to submit comments regarding S. 1074, the "Pesticides in Food Safety Act of 1991," as well as pesticide-related food safety issues generally as an integral component of successful national food policy.

In our comments, we hope to accomplish three interrelated objectives:

1. Advocate improvements in food safety within the context of overall, national food policy objectives;
2. Describe the unique partnership between farmers and the cooperatives that they own, and pro-active programs which provide valuable technical assistance that help farmer-members utilize crop protectants more safely and effectively;
3. Offer our views on the proposed legislation.

INTEREST OF THE NATIONAL COUNCIL

The National Council of Farmer Cooperatives is a nationwide association of cooperative businesses which are owned and controlled by farmers. Its membership includes over 100 agricultural marketing, supply and credit cooperatives, plus 32 State councils. National Council members handle practically every type of agricultural commodity produced in the United States market these commodities domestically and around the world, and furnish production supplies and credit to their farmer members and patrons. The National Council represents about 90 percent of the nearly 5,000 local farmer cooperatives in the nation, with a combined membership of nearly 2 million farmers.

The farmer cooperative community includes food processors and distributors, as well as farm input suppliers. Cooperatives account for 80 percent of the milk and a large portion of the cotton, grain and soybeans produced in the United States. A large share of the fruits, nuts and vegetables on supermarket shelves, and ultimately on dinner tables, arrived there through the efforts of cooperatives. Cooperatives also are in the important business of supplying farmers with fuel, fertilizers, crop protectants, feed, seed and other important elements of production.

Cooperatives are unique in the agribusiness community, in that farmer-members comprise the ownership. Farmers and their families are also consumers who have a direct stake in ensuring that the food products they consume are safe. Additionally, as stewards of the land, farmers are "front line" environmentalists, striving for sound ways to produce food while protecting the natural resource base for themselves and future generations.

The National Council believes that the U.S. food supply is among the safest in the world, and supports responsible efforts to make the food supply even safer. The

issue of food safety impacts virtually every segment of the National Council membership—the producer-members who rely on and utilize agricultural chemicals, as well as the cooperatives responsible for supplying them—and processing and marketing cooperatives which are concerned about their ability to deliver a safe, high quality product to the retail shelf and ultimately the consumer.

FOOD POLICY OBJECTIVES CRITICAL INGREDIENTS OF DEBATE OVERAGRICULTURE'S USE OF CROP PROTECTANTS

If the National Council could add one dimension to the discussion concerning food safety, it would be to urge that full consideration be accorded to possible impacts on food policy before decisions are made. As indicated in Attachment 1, entitled "Food Policy in Perspective," the National Council believes that the continued well -being and security of the United States is dependent on our ability to continue providing consumers with a safe, dependable, adequate supply of food at reasonable prices. This is the fundamental national food policy that we have in place today.

We would submit that the key to success in any legislation on food safety is the achievement of a difficult but critical balance between moving forward with needed improvements in the food safety arena, while at the same time remaining sensitive to the need for maintaining access to crop protectants and other critical inputs that are so necessary for the continued success of American agriculture in sustaining vital food and agricultural policy objectives.

FOOD SAFETY LEGISLATIVE OBJECTIVES

With this larger perspective in mind, the National Council recommends that legislation on food safety be enacted which responds to the following interdependent objectives:

1. Establish the Federal Government with primary responsibility for ensuring the safety of our food supply by providing for nationally uniform tolerances, including any related labeling considerations;
2. Provide for establishing regulations on the basis of sound, scientific evidence, together with improvements in monitoring and testing, with equal enforcement for domestically produced and imported food;
3. Ensure that food safety-related decisions reflect the need for agriculture to maintain access to the diverse range of critical crop protection chemicals and other alternatives that are necessary to combat aggressive and highly adaptable crop pests on a sustainable basis;
4. Provide for increased research and extension efforts aimed at maintaining agriculture and the food industry's ability to provide consumers with a dependable, safe and wholesome supply of food at reasonable prices in an environmentally sound way; and
5. Provide the necessary resources to allow the Federal Government to better communicate what is being done to protect consumers and the public at large with regard to the safety and wholesomeness of our food supply.

We believe coordinated action on these fronts offers real potential to (1) achieve needed improvements in food safety policy, and (2) maintain consumer confidence, both in the safety of our food supply and in the ability of the Federal Government to protect consumers' interests.

TECHNICAL ASSISTANCE AND QUALITY CONTROL ACTION PROGRAMS

Cooperatives in their special partnership with farmer-members treat the critical food safety and environmental responsibilities which accompany our food mission most seriously. Cooperatives have responded to food safety and environmental challenges in a number of ways.

By way of example, the National Council would like to share briefly with the Committee some highlights about the operations of Cenex/Land O'Lakes Ag Serices. We do so for two reasons:

1. First, we would respectfully submit that success in achieving food safety goals starts in the field, through the day-to-day dedication and commitment of those who must produce that food—American farm families.
2. Second, a number of significant provisions in the proposed legislation being considered by the Committee are based at least in part on critical assumptions about how pesticides are used in farm production. Consideration of how contemporary ag-

riculture operates may be helpful to the committee in deliberating the appropriateness of those assumptions.

Cenex/Land O'Lakes Ag Services is a farm supply and technical services joint venture involving Cenex and Land O'Lakes, both of which are farmer-owned cooperatives. Their 300,000 farmer-members in the upper Midwest and Pacific Northwest are served through a network of 1,250 locally owned and control led cooperatives.

Cenex provides petroleum products to farmer-members. Land O'Lakes takes high quality milk produced by dairy farmers in the Midwest and helps them achieve higher returns for their milk by manufacturing and marketing dairy products under the national brand name. However, many people aren't aware that these cooperatives also work with farmers who raise corn, soybeans, wheat and other crops, providing them with plant foods crop protection products and technical services. That's the portion of their business that we'd like to describe for you today.

The Cenex/Land O'Lakes Ag Services environmental mission statement that drives the cooperative in its everyday operations, reads as follows: "To actively and responsibly support stewardship of our natural resources, while maintaining a positive balance between the environment, the economic well being of agriculture and global food needs."

Scientific information management is a major part of this cooperative sanction program to assist farmers in carrying out this important mission. Some of the nation's leading experts are employed to help the cooperative system develop a proactive approach to environmentally sound crop production practices.

Computer programs have been designed and provided to local cooperatives that can combine extensive data on crop protection products and nutrients with individual field histories, yield goals and other pertinent data. Farmers can plug into this sophisticated system and tailor the soundest application rates on a field by field basis. In addition, local cooperatives have access to important information and assistance through Cenex/Land O'Lakes, which closely tracks changes in pesticide and other environmental, regulatory compliance requirements.

Furthermore, Cenex/Land O'Lakes has made a major commitment to provide increased "hands on" assistance to farmer-members. For example, more than 300 trained field technicians working through local co-ops are available to work directly with individual farmers from planting through harvest in conducting soil tests, evaluating pest problems and advising on Best Management Practices.

Best Management Practices, or BMP's, is a term now commonly used in referring to a range of proven, scientific crop management practices which help farmers control production costs and protect the environment. Integrated Pest Management, or IPM, is one type of BMP which involves a philosophy of reducing chemical pest controls while sustaining food production. IPM techniques include increased crop monitoring, pesticide applications targeted at specific pest infestations, and the development of new genetic and biological pest controls. For example, one approach involves the introduction of "good bugs" to eat "bad bugs."

Other cooperatives are making similar commitments in partnership with their farmer-members. Different approaches best fit the special circumstances of various farming systems and regions. Cooperatives' continuing goal is to work alongside the research community in looking for improved ways of producing a safe, dependable, adequate, food supply at reasonable prices, in an environmentally sound manner.

The cooperative community is justifiably proud of its role in going well beyond the "letter of the law" by attempting to respond to its true spirit through aggressive programs contributing to the responsible and efficient use of crop protectants, and the resulting demonstrated safety record of this Nation's food supply.

The National Council believes this is a positive story worth sharing with others involved in the food safety debate, as it may prove helpful as we all strive to craft workable solutions. Members of the committee are welcome to experience this story firsthand. We would be pleased to arrange for you to visit with the real people who make it happen—farm families and cooperative managers—as well as observe the programs we have described in operation.

VIEWS ON S. 1074

It is within the context of cooperatives' hands-on involvement in the science of food production and a firm conviction that needed food safety improvements must occur as a coherent component of food policy that the National Council offers comments on the proposed legislation (S. 1074). National food policy objectives have been and continue to be to provide consumers with a safe, wholesome, dependable and abundant supply of food at reasonable prices. The overriding question we at-

tempted to address in reviewing S. 1074 is whether the proposal would make needed food safety advances and allow American agriculture to continue fulfilling these important objectives.

We cannot predict exactly what would occur under this proposal if it were to become law, and it is ultimately up to the scientific community to puzzle over the critically important question of which pesticides or classes of pesticides might be lost. But it is possible for us to evaluate the appropriateness of the various provisions, as to their likely practical effects.

S. 1074 advances a number of conceptual approaches that offer considerable potential to improve existing law. Most notably, the National Council applauds the effort to apply a single, negligible risk standard for both raw and processed foods. Elimination of the so-called "Delaney paradox," created by conflicting provisions in Sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA), is long overdue.

We must point out, however, several provisions which we believe would function in a manner that would jeopardize interrelated food policy and safety objectives:

First, the proposed use of arbitrary quantitative standards in rigid formulas implies a level of accuracy and degree of sophistication which simply do not exist in the scientific arena of evaluating risks associated with long-term exposure to extremely low levels of pesticide residues.

This is compounded by the required use of assumptions about pesticide application practices and exposure that clearly do not reflect what is known. A "cookbook" approach in automatically applying pesticides to 100 percent of the crop, at the maximum rate on the label, is clearly not the practice in most of agriculture.

For example, in most instances applications are avoided entirely when possible, and when necessary are targeted in response to infestations above economic threshold levels. In addition, residue levels on foods tested prove overwhelmingly to be either zero or well below the maximum allowable. We are confident that surveys currently being conducted by the U.S. Department of Agriculture and the Environmental Protection Agency (EPA) will reaffirm these assertions.

While the methodologies for risk assessment are the best currently available, they are based heavily on theories and presumptions that are distinctly lacking in verifiable precision. There are no actuarial data of which we are aware to support assertions that theoretical risks are representative of actual risks faced by consumers. The policy decision process using such methodologies should reflect their limitations.

Second, our concern about these deficiencies is magnified by the fact that the bill utilizes the risk calculations in establishing a sharply defined risk threshold in a manner that would override other legitimate considerations, including the many benefits that legitimate use of pesticides offers. Health, nutrition, agricultural and other consumer benefits should be part of the equation in determining whether a tolerance should be permitted for a pesticide residue in food products. While such benefits may not be readily quantifiable, they are both legitimate and critical.

Third, it would seem desirable policy to reconcile differences in the major statutes governing pesticides. The proposed bill takes an important step in this direction by attempting to remedy inconsistencies within the FFDCA. However, it would make the FFDCA even less compatible with the other major statute governing pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Specifically, S. 1074 proposes a reevaluation of all food-use pesticides on an accelerated time schedule which we believe is unworkable. It virtually ignores a comprehensive pesticide reregistration schedule already in operation as a result of the 1988 FIFRA amendments. That schedule is already taxing the resources of the EPA and industry.

Fourth, S. 1074 is silent on the issue of national uniformity in setting tolerances for pesticides, as well as related food labeling considerations. The federal government should act upon its responsibility to forge needed improvements in food safety, based on sound science. State and local efforts, while well-intentioned, would likely add to fear and confusion on the part of consumers, and add to food costs by seriously disrupting interstate commerce.

The National Council is deeply concerned that the bill as proposed would have the unintended effects of reducing access to critical pesticides, jeopardizing food policy objectives and increasing food costs—without significantly increasing the safety of our food supplies.

It would not be any single action, but rather an accumulation of individual regulatory decisions under the proposed system and guidelines. In particular, minor use pesticides, which are instrumental in the production of nutritious fruits and vegetables so essential for a healthy diet, would be placed at risk. Agriculture is already

facing serious challenges in retaining critical minor use pesticides and developing new ones under the existing FIFRA reregistration schedule.

CONCLUSION

In closing, the National Council of Farmer Cooperatives believes that the nation would be well served through enactment of legislation which would achieve consistent and nationally uniform improvements in FFDCA and FIFRA, with consideration of food safety needs in the broader national policy context of food policy. Legislation must be balanced and address all key components if it is to work. By way of example, the best designed food safety standards would constitute a failure if food shortages or price increases result from loss of critical pesticides. And, the benefits of effective Federal pesticide standards would be severely undermined if 50 different State standards were to follow.

We respectfully submit that while the objectives of S. 1074 are laudable, its contents must undergo significant revision to achieve the necessary balance to accomplish desirable food/safety policy goals.

We stand ready to work with members of this committee toward the important objective of balanced, workable food safety legislation. We would reiterate our invitation to each of you to come out and visit a cooperative and its farmer-owners, to help you gain a better appreciation of the job we must do in producing abundant, high quality, affordable—and we believe safe—food for the dinner tables of your families and ours.

Thank you, Mr. Chairman, for this opportunity to present our views. We respectfully request that this statement be included as part of the July 10, 1991 hearing record.

CHART 1

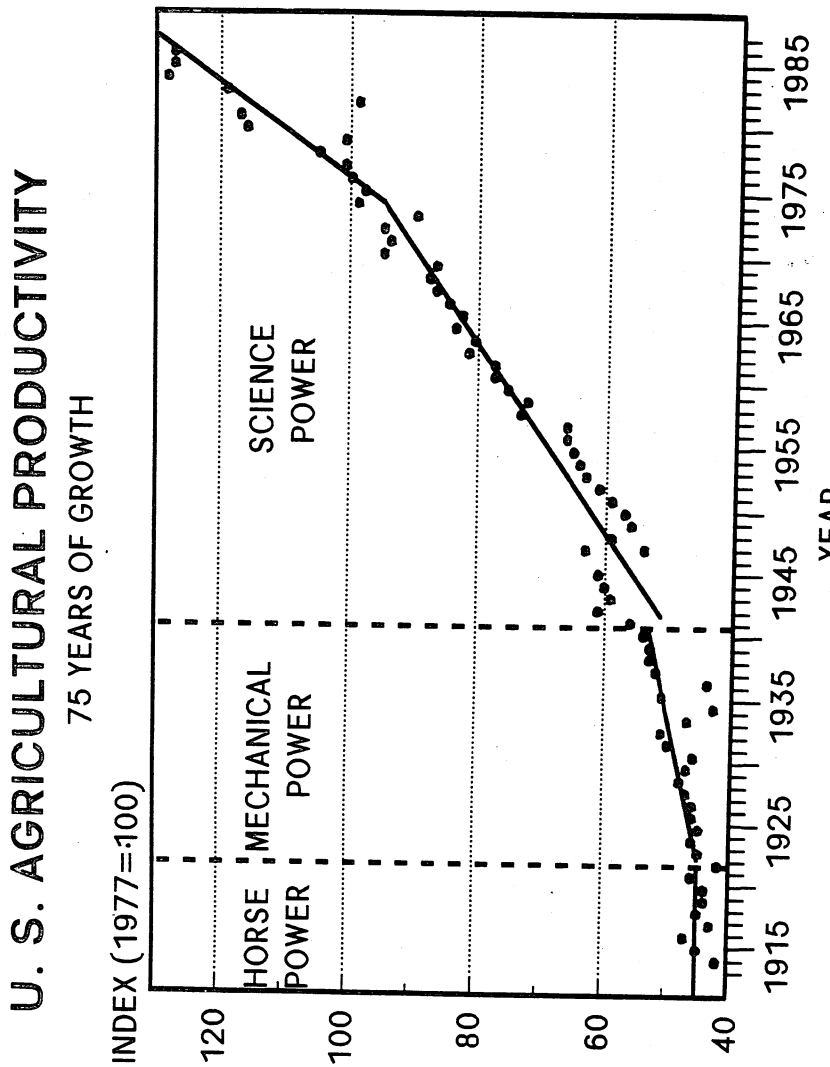
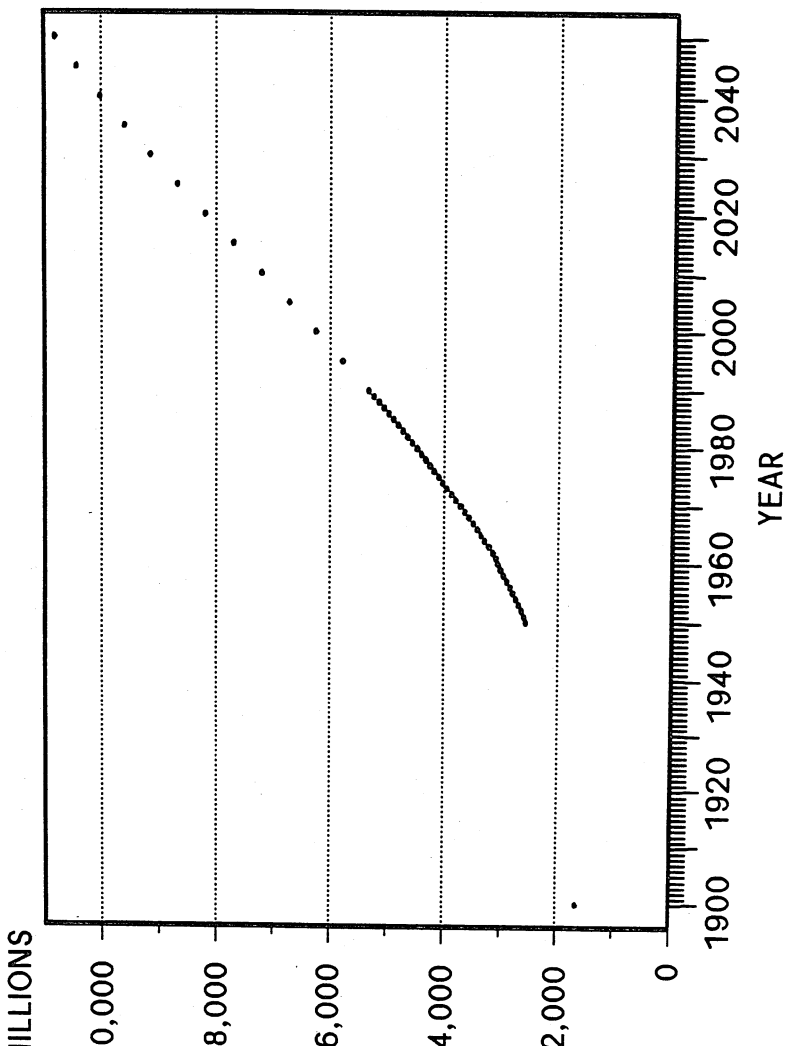

U. S. AGRICULTURAL PRODUCTIVITY
75 YEARS OF GROWTH
INDEX (1977=100)
120
100
80
60
40
HORSE POWER
MECHANICAL POWER
SCIENCE POWER
1915
1925
1935
1945
1955
1965
1975
1985
YEAR

CHART 2


WORLD POPULATION GROWTH
MILLIONS
10,000
8,000
6,000
4,000
2,000
0
1900
1920
1940
1960
1980
2000
2020
2040
YEAR

Attachment 1--June 19, 1991 Testimony June 1991

FOOD POLICY IN PERSPECTIVE*

It is essential to remember that one of the primary responsibilities of the federal government is to assure the citizens of this country a safe, wholesome and dependable supply of food at reasonable prices. However, because of our international leadership, this responsibility goes even beyond our borders to the world.

With the limitations on resources such as land and water combined with the increased demand for food associated with population growth and the need for improved diets, the task we face in achieving such a food policy is enormous and should not be taken lightly.

We have made progress meeting this policy goal. World food production has increased at a rate of 2.5% since 1950 compared with a population growth rate of 1.9%. This means that on a per capita basis people have more food available to improve their diets at a rate of .6% per year. Fortunately, about 75% of this increase has come from gains in productivity or higher output per unit of input. With continued increases in the cost of inputs, such productivity gains have helped hold down average unit costs and thus the cost of food to consumers.

This is dramatically illustrated by the continued decline in the share of income spent on food by the citizens of this country. For example in the early 1960's U.S. citizens spent nearly 18% of their disposable income on food. Now our citizens spend only about 12% of their income on food. The rate of increase in the cost of food has been less than the rate of increase in disposable income.

This could not have been achieved without continued gains in productivity. This is illustrated in Chart 1, which traces the gains in productivity as we have moved from horse power to mechanical power to science power. It is clear that in order to meet the continued growth in world population shown in Chart 2 with increasingly limited resources, the growth trends associated with science power are critical for the future. Failure to do so could have substantial implications on our ability to meet future food needs at affordable prices.

*Policy statement by National Council of Farmer Cooperatives

Food Policy Perspective (cont.)--

To illustrate, consider the fact that the farm value of food represented 40% of the retail cost of food in the early 1960's compared with about 25% last year. Without continued increases in productivity and efficiency this could not have been achieved.

Unfortunately, these averages do not tell the entirety of the story that must be taken into account when considering actions that result in less productivity and efficiency and thus higher consumer food costs. While the average income spent on food in the U.S. is only about 12 percent, there are 16.8 million households in the lowest income category that spend nearly 57% of their income on food. These households represent 32 million people or 13% of our population.

Even with programs such as food stamps, WIC, and school lunch, many of those in the lowest income level still have inadequate diets and thus in many cases suffer health and disease problems associated with malnutrition. If this is true in the U.S. where the average income is over $20,000 per year and food accounts for an average of only 12%, imagine the implications in countries around the world where the population growth rate is much higher, the average income is much lower and the share of income spent on food is much higher.

Despite the progress we have made, agriculture must accomplish even more. However, future gains are going to be more difficult. World population is projected to continue to grow at a rate of about 1.9% per year. This means that by the year 2000 there will be another 1.0 billion people that must be fed. Food must not only be available, it must be available at affordable prices. In order to do this we must continue to make progress in the area of agricultural productivity.

The agricultural community has long recognized that in order to accomplish food policy objectives on a continuing basis, the agricultural economy and its resource base must be sustainable. The responsible use of pesticides and other critical inputs, in a manner that protects the environment and ensures a safe food supply, thus has been an ongoing agricultural policy objective.

A number of proposals are now being made in the areas of food safety, ground water and air quality that could have adverse implications for the ability of the food industry to continue to make progress in meeting the food policy goal outlined above. While everyone agrees that we should continue to make improvements that assure safe food, clean water and clean air it is essential that they be done in a way that also assures that our food needs continue to be met.

Food Policy Perspective (cont.)--

We are in peril that safety and environmental issues will be looked at in isolation without consideration of their full implication on food availability and cost. We cannot micro-manage all these issues. They must be evaluated in the context of their impact on the food system and thus on our ability to meet the food needs of consumers at home and abroad.

Food Safety Debate

The current debate on food safety revolves around the standards for pesticide residues and whether or not they need to be changed.

Several important questions to consider are:

1) Are the current standards appropriate if effectively monitored and enforced?

2) If the standards are not appropriate, then what changes need to be made and what are the implications for meeting our overall food policy objective?

3) Is our current system for testing and reporting adequate?

4) Does the public understand the extent of current safeguards the government and industry provide to assure a safe food supply?

Given the fact that the federal government has the responsibility to assure that our food needs are met, it is believed that the issue of food safety should be viewed as a major component of an overall food policy. With this in mind we recommend the following action:

1) Charging the federal government with primary responsibility for assuring the public that the food industry is providing a safe, dependable supply of high quality food and natural fiber at reasonable prices;

2) Supporting efforts to strengthen the federal government's food safety role, with consistent standards for both domestically produced and imported food (i.e. improved standards, monitoring, and testing);

Food Policy Perspective (cont.)--

3) Ensuring that food safety-related decisions reflect the need for agriculture to maintain access to the diverse range of critical crop protection chemicals and other alternatives that are necessary to combat aggressive and highly adaptable pests on a sustainable basis;

4) Supporting increased research and extension activities aimed at maintaining agriculture's ability to provide consumers with a dependable, safe and wholesome supply of food at reasonable prices in an environmentally sound way;

5) Providing the necessary resources to allow the Federal government to better communicate what is being done to protect consumers and the public at large with regard to the safety and wholesomeness of our food supply.

These actions, it is believed, are essential if we as a nation are to continue to meet our food policy objectives and if public confidence in the safety of our food supply is to be maintained and strengthened.

PREPARED STATEMENT OF THE AMERICAN FROZEN FOOD INSTITUTE

The American Frozen Food Institute (AFFI) welcomes this opportunity to comment on S. 1074—the Safety of Pesticides in Food Act of 1991. AFFI is the national trade association representing frozen food processors. AFFI members produce approximately 80 percent of the nation's total yearly production of frozen foods, and process numerous agricultural commodities that are produced with the benefit of pesticides. Any change in the manner in which pesticide tolerances are regulated by the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) would have a significant impact on the frozen food industry.

AFFI and its member companies have a long-standing commitment to the safety of frozen foods. AFFI has consistently endorsed efforts to modernize the food safety laws, especially as they relate to the regulation of pesticides used on raw agricultural commodities and in processed foods. The goal of our food safety laws is to ensure that safe foods are readily available to consumers while unsafe substances are not permitted in foods or are removed from the marketplace without delay. Indeed, it is the experience of the frozen food industry that there are either no pesticide residues in frozen foods or the residues are well within the established tolerances. AFFI is committed to continuing its work with other segments of the food industry to ensure that only minimum amounts of pesticide residues are present in foods.

While reform of our food safety laws is certainly appropriate, lawmakers must take great care to ensure that changes are based on sound, flexible scientific principles that protect the public health while not jeopardizing the availability of an abundant, safe, and wholesome food supply. There are several proposed provisions embodied in S. 1074 that would promote this end—including a single negligible risk standard applicable to both processed foods and raw agricultural commodities, and the ability to continue marketing foods when a pesticide tolerance is modified or revoked—and AFFI endorses these elements of the bill. AFFI, nonetheless, opposes S. 1074 on the grounds that the bill would establish a negligible risk standard that is unrealistic and scientifically unsound for measuring risk, would prohibit the consideration of a pesticide's benefits in establishing tolerances, and would fail to establish a national uniform standard that governs the adoption of pesticide food residue regulations.

PESTICIDE RESIDUES ON RAW AGRICULTURAL COMMODITIES AND INPROCESSED FOODS SHOULD BE REGULATED UNDER THE SAME SAFETY STANDARD

AFFI supports the provision in the proposed legislation that would regulate pesticide residues both on raw agricultural commodities and in processed foods under a single "negligible risk" standard. Evaluation of all such food tolerances should be conducted under a unified standard which is not dependent on the form of the product.

Under current law, EPA may establish a tolerance for a pesticide residue on a raw agricultural commodity that is deemed safe even if the pesticide is known to be carcinogenic but is safe nonetheless. That tolerance applies to the pesticide residue in a processed product made from the raw agricultural commodity and will not render the finished product adulterated. If, upon processing, the residue becomes concentrated at a level higher than the established tolerance, however, the higher amount is considered to be a food additive and is subject to the same safety criteria that all food additives must satisfy. A carcinogenic pesticide residue at this higher level must be banned, therefore, because the Delaney Clause—which prohibits the use in food of any additive found to cause cancer in man or animals regardless of level of risk—applies to food additives but not to pesticide residues on raw agricultural commodities. This result is known as the "Delaney Paradox."

S. 1074 would provide for the establishment of tolerances for pesticide residues in accordance with one set of criteria, consistent with the recommendations of the National Academy of Sciences, regardless of whether the residue is on the raw agricultural commodity or in the processed food. AFFI fully supports legislative efforts to resolve the Delaney Paradox and ensure that all foods are regulated under a uniform standard for establishing tolerances.

"NEGLIGIBLE RISK" STANDARD SHOULD BE REDEFINED

The zero-risk standard characteristic of the Delaney Clause is simply unrealistic and scientifically unsound in light of modern methods enabling the detection of sub-

stances and evaluation of risk at minute levels. It is appropriate, therefore, that this standard be replaced with a negligible risk approach whereby foods could not contain pesticide residues presenting greater than "negligible risk." A negligible risk standard has been relied upon by EPA in the context of its pesticide reregistration and tolerance reassessment programs, and was endorsed by an expert report of the National Academy of Sciences. AFFI opposes the negligible risk standard as proposed in S. 1074, however, because it would define that standard numerically in the law leaving no room for EPA to exercise scientific judgment.

It is unwise public policy to cast in stone a safety standard that is inflexible. Food safety determinations involve a number of complex factors that are unique to each pesticide use. Flexibility in determining safe use levels for a particular pesticide is, therefore, essential. The bill's overly proscriptive approach would preclude EPA from exercising its independent judgment in regulating pesticide residues. In addition, an unduly restrictive safety standard could reduce the availability of many minor use pesticides that pose less than a negligible safety risk.

The assessment of risk is a science-based inquiry subject to change as analytic procedures and the underlying knowledge concerning health risks associated with the use of pesticides evolves. The proposed bill would commit to statute an overly conservative standard that would have to be continually modified and revised by Congress if the standard were to keep pace adequately with advances in science. As a result, the proposed standard would not enhance the safety of food and would most certainly preclude the use of pesticides in many cases where such use would appropriately be deemed safe under a more flexible and realistic negligible risk approach.

EPA SHOULD BE PERMITTED TO CONSIDER THE BENEFITS OF PESTICIDES IN ESTABLISHING TOLERANCES

S. 1074 would prohibit EPA from taking into account the benefits of a pesticide, including its effects on the costs and availability of food in establishing a tolerance for the pesticide on the raw agricultural commodity or in the processed food. Currently, EPA is authorized by statute to consider the benefits of pesticides in setting tolerances. This is in recognition of the useful function pesticides play in crop production. EPA should retain the ability to consider these benefits, while at the same time ensuring that the use of pesticides does not pose an undue public health risk.

To ignore the benefits of a pesticide is naive and contrary to the public interest. Pesticides are used primarily to promote the growth of strong and healthy crops. Pesticides are needed to prevent insect infestation, plant disease, and other growth of bacteria, all of which threaten the very existence of agricultural crops. Rational pesticide residue regulation is necessary to ensure the availability of many foods that health officials are urging consumers to eat. Particular care must be taken to ensure that the benefits of pesticides used on "minor use" America, are considered as well. Most frozen foods, with the exception of crops such as corn, are considered minor use crops and, therefore, would not be likely to receive the attention needed from chemical manufacturers should existing products which provide important benefits be removed from the market.

Overall, pesticides provide many important benefits to farmers, food processors, and the ultimate consumer. These benefits are not limited to economics, but involve nutritional quality and availability of food as well. Regulators must be permitted to consider these benefits in setting tolerances.

EFFECTIVE FEDERAL FOOD SAFETY REGULATION REQUIRES NATIONAL UNIFORMITY

Consistency in all food safety laws is crucial to the viability of the food industry and the public interest. The continued ability of States to enforce different and sometimes conflicting risk standards and, therefore prohibit the sale of foods containing residue levels deemed safe by EPA, would undermine the Federal Government's ability to regulate the food supply effectively in accordance with rules that are predictable and uniformly applied throughout the country.

Food processors and manufacturers are, with increasing frequency, subject to a wide range of State and local food safety laws. Often, these laws impose vastly divergent requirements and make interstate shipment and sale of identical products extremely burdensome to the food manufacturing and processing industry. For example, labels and ingredients must constantly be evaluated for compliance with various state and local requirements. The results are consumer confusion, loss of con-

sumer confidence in the food supply, and substantial and unjustifiable costs burdening an otherwise very efficient food distribution system.

SUMMARY

Americans receive the safest and most abundant food supply in the world. Much of the credit for this goes to the responsible use of pesticides. AFFI supports the review of current laws to ensure that consumers continue to have available a variety of safe, wholesome, and economical foods. AFFI, nonetheless, opposes S. 1074 because it would imposed impractical risk assessment standards and prohibit the consideration of important benefits in establishing pesticide tolerances. Congress should make certain that any reforms in our food safety laws will ensure a safe, abundant food supply. Unfortunately, S. 1074 fails to meet this objective.

PREPARED STATEMENT OF THE U.S. CHAMBER OF COMMERCE

The U.S. Chamber of Commerce appreciates this opportunity to express its views on S. 1074, the Safety of Pesticides in Food Act of 1991.

The Chamber includes among its membership all links In the food chain from agrichemical manufacturers and other farm suppliers to growers, processors, wholesalers, and retailers. Our perspective is the good of the food system as a whole—a system that accounts for roughly one seventh of total gross national product, more than 9 million jobs, and the economic well-being of hundreds of rural communities. The ultimate link in the food chain is the consumer, whose confidence has been shaken in recent years by a series of media reports about health risks in the food supply—many of which involve pesticide residues.

The Chamber supports legislation to restore confidence in the food supply by harmonizing and modernizing health and safety regulations on the basis of the best available science. Consequently, we commend the committee for its diligent efforts to address the " Delaney paradox" and develop a consistent risk standard for both raw and processed foods. S. 1074 is a step in that direction. However, we suggest that this bill would be improved by several additions or changes.

NATIONAL UNIFORMITY

Under current law, States have the authority to set tolerances for pesticide residues in food that are more stringent than those established by EPA. This is a disabling policy for domestic and international food trade. When States set tolerances inconsistent with national standards and hose of other States, the result is consumer confusion, substantial disruption of interstate commerce, and complications in international trade. We learned this lesson at great cost during the ethylene dibromide (EDB) incident of 1983.

States are an important factor in the food safety equation, and their considerable personnel and technological resources are needed to help regulate the food supply. For this reason, States should be allowed to participate in the national, science-based process of tolerance-setting. However, States should not have authority to set inconsistent tolerances, except where special local circumstances dictate. The Chamber supports adoption of the President's proposal, outlined in his 1989 Food Safety Plan, that national uniformity for tolerances be established. We respectfully urge the committee to make this provision a part of S. 1074.

NEGLIBLE RISK AND RISK ASSESSMENT

S. 1074 recognizes that the 1950'sra science reflected in the "zero risk" Delaney Clause cannot be applied constructively in today's scientific context. In its place, S. 1074 substitutes a negligible-risk standard of one-in-one million probability of cancer over a lifetime of exposure. This definition of negligible risk should serve as a target or benchmark rather than a statutory mandate. At present, cancer risk assessment involves extrapolations from animal studies based on a string of conservative assumptions about the shape of the dose response curve at very low doses. Flexibility is needed, not only to accommodate future advances in the ever-evolving science of risk assessment, but also to give regulators discretion to factor in their non-quantifiable professional judgements and experience. This discretion does not imply a lowering of standards. In some cases, it may result in the rejection of a product that otherwise would have to be approved under the numerical standard imposed in S. 1074.

A related concern is the use of even more conservative risk-assessment guidelines. Under S. 1074, regulators would have to assume that all pesticides approved for use on a crop have been used and that residues are present at full tolerance levels. This is rarely the case in practice. If these extremely conservative guidelines are adopted, regulators will need a measure of flexibility in determining risk. Otherwise, many safe products will be eliminated from the food production system.

CONSIDERATION OF BENEFITS

S. 1074 would not allow consideration of benefits—even health and nutrition benefits—in tolerance determination. Pesticides have made it possible to provide consumers with a nutrient-rich diet of fruits, vegetables, ad fiber throughout the year at affordable prices. These benefits should continue to be taken into account.

IMPACT ON MINOR-USE PESTICIDES

Minor-use pesticides are essential to crop production. Without the availability of these low-volume, low-profit products, fruit, vegetable and other specialty crop growers will be in severe jeopardy. During recent congressional hearings on implementation of the 1988 FIFRA amendments, we learned that the reregistration process mandated by those amendments is having an unintended adverse impact on minor-use pesticides. Because of the high costs associated with reregistration of these low-revenue-producing products, many manufacturers are deciding not to reregister their minor-use products, resulting in their cancellation.I11S. 1074 would unintentionally add to the problem of minor-use pesticides by substantially increasing the manufacturers' costs of securing and maintaining minor-use registrations. The bill would require the payment of fees, including annual maintenance fees, to cover all EPA costs associated with issuing and reevaluating pesticide tolerances.

CONCLUSION

The Chamber supports the Committee's efforts to address the Delaney Clause and resolve conflicts and inconsistencies in the regulation of pesticide residues, but we cannot support S. 1074 in its present form. We respectfully urge you to consider the problems discussed above and make the needed improvements during the mark-up process.

Thank you for this opportunity to comment upon S. 1074, the Safety of Pesticides in Food Act of 1991.

PREPARED STATEMENT OF THE UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

The United Fresh Fruit and Vegetable Association is the national trade organization representing all sectors of the fresh fruit and vegetable industry. Founded in 1904, United's core membership represents over 2,100 member companies throughout the United States. Our membership consists of grower/shippers, wholesalers, importers, exporters, retailers and foodservice operators.

The United Fresh Fruit and Vegetable Association appreciates the opportunity to submit written comments expounding our views on the "Safety of Pesticides in Food Act of 1991," which has a direct impact on the fruit and vegetable industry and are sorry we were not able to testify orally before the committee. Our association fully supports the passage of new food safety legislation to assure American consumers a safe, wholesome, and plentiful food supply, to give our regulatory agencies necessary authority to remove hazardous pesticides from the market in an expedient manner, and to assure fruit and vegetable producers and marketers a more placid and predictable future. Although S. 1074 addresses the safety of pesticides in foods, it's provisions as currently written create very real concern in the minds of many in the produce industry. The following paragraphs will highlight a few of these misgivings.

First, the fresh fruit and vegetable industry must maintain and even regain the confidence of the American public. The recent wave of food scares has devastated parts of our industry and created a credibility gap that is resistant to repair. It is the responsibility of the food industry to provide an array of safe, healthful, nutritious, and affordable foods to the marketplace. It is the responsibility of government to set stern, uniform standards which define the safety of the food we grow and supply to the American public. A necessary balance is needed.

Second, we must clearly define what constitutes a real versus a theoretical health risk. Risk determinations must be based on sound science and realistic exposure es-

timates. As mandated by FIFRA '88, the EPA is requiring that substantial amounts of new data be submitted in its efforts to re-examine the safety of older chemicals. These new studies are replacing older, less sophisticated ones. New, more sensitive, methods of detecting pesticide residues in food are replacing mathematical modeling. Market basket surveys are replacing field residue studies to estimate pesticide residues "at the dinner plate." The EPA is asking our growers for benefit and use information to be incorporated into its regulatory decision-making. Clearly, the trend is moving toward making regulatory decisions based on more realistic assumptions.

Third, we need to set uniform risk standards while retaining the flexibility needed to make balanced decisions. We support replacing the antiquated Delaney Clause with a uniform negligible risk standard, but we oppose assigning a specific number of definition of risk to it. Such a restriction would disallow consideration of future technological advances in pesticide detection and would prevent EPA from making regulatory risk decisions on a case-by-case basis—taking into account pesticide benefits—thus potentially resulting in the loss of valuable pesticides used on fresh fruit and vegetable crops.

Fourth, we advocate a national pesticide tolerance uniformity provision to preempt State laws that conflict or differ with national standards. We cannot win the confidence of the American public if every State has a different "allowable limit of pesticide reside" on commodities they grow. Nor can we realistically expect to market across State or national boundaries. The legislation should also preempt indiscriminate use of health and safety warnings which undermine the safety of our food supply.

Fifth, we agree that the EPA should be allowed to move quickly to remove hazardous pesticides from the market without being endlessly fettered in regulatory red tape. We generally support streamlining the cancellation procedure by replacing the lengthy hearing process with a notice and comment period. However, when a tolerance is revoked we concur with you that a "pipeline" provision be provided to allow for the marketing of a legally treated food.

We support suspension authority but stress that this vehicle should only be used in situations where there is a true "imminent hazard" objectively identified by the best available science. Misuse of this regulatory tool would create unnecessary public hysteria and result in unjustified damage to the promotion and marketing of otherwise safe and healthy produce.

And last, we fully support legislation that would provide necessary assistance to our members who produce "minor crops." As a result of FIFRA '88, many chemical producers (lacking financial incentives to produce data and pay fees for small volume chemicals) are dropping registrations for chemicals that our industry must have. We generally advocate reducing data requirements for minor use crops, combining data requirements, waiving fees, and providing the opportunity for grower groups to become registrants themselves. Your bill would increase fees for tolerance and maintenance registrations and would give EPA authority, at any time, to require additional health and safety data to support tolerances. A provision such as this would result in even more pesticides for minor crops disappearing from the marketplace.

These are changes our industry advocates in a comprehensive food safety bill. If we are to continue to enjoy a safe and varied array of fresh fruits and vegetables, we must act now to ensure that our standards remain consistently high; that our growers are given the support they need to produce safe, quality produce; and that our regulatory system is strong, yet flexible. Again we appreciate the opportunity to submit written comments to this committee. We look forward to working with you in crafting legislation that addresses all our concerns.

The CHAIRMAN. The committee stands in recess.

[Whereupon, at 12:30 p.m., the committee was adjourned.]

○

ISBN 0-16-035800-0

90000

9 780160 358005