PESTICIDE REGULATORY REFORM AMENDMENTS OF 1989 AND THE FOOD SAFETY ASSURANCE ACT OF 1989

HEARINGS

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

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ON

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CONTENTS

	Page
H.R. 3153, a bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act	432
H.R. 3292, a bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes	465
Brown, Hon. George E., Jr., a Representative in Congress from the State of California; opening statement	2
Prepared statement	3
de la Garza, Hon. E (Kika), a Representative in Congress from the State of Texas, opening statement	1
Remarks of	101
Grandy, Hon. Fred, a Representative in Congress from the State of Iowa, opening statement	14
Morrison, Hon. Sid, a Representative in Congress from the State of Washington, opening statement	17
Olin, Hon. Jim, a Representative in Congress from the State of Virginia, opening statement	16
Roberts, Hon. Pat, a Representative in Congress from the State of Kansas, opening statement	15
Letter of October 18, 1989	27
Stenholm, Hon. Charles W., a Representative in Congress from the State of Texas, opening statement	5

WITNESSES

Benbrook, Charles M., Executive Director, Board of Agriculture, National Research Council, National Academy of Sciences	90
Prepared statement	372
Bloom, Anne W., staff attorney, Congress Watch, Public Citizen	55
Prepared statement	308
Botts, Daniel A., manager, environmental and pest management division, Fruit and Vegetable Association, statement	351
Duerksen, Greg, vice president, marketing and development, Terra International Inc., and chairman, food safety committee, Chemical Producers and Distributors Association	42
Prepared statement	224
Feldman, Jay, national coordinator, National Coalition Against the Misuse of Pesticides	49
Prepared statement	250
Fuquay, Claudia R., director, congressional relations, United Fresh Fruits and Vegetable Association	78
Prepared statement	343
Grazer, Walter E., policy advisor, food and agricultural issues, United States Catholic Conference	56
Prepared statement	316
Griffin, Rusty, president, Griffin Corp., and chairman of the board, Chemical Producers and Distributors Association	41
Prepared statement	214
Heldman, Dennis R., executive vice president, scientific affairs, National Food Processors Association	70
Prepared statement	322
Hind, Rick, Environmental Program Director, U.S. Public Interest Research Group	52
Prepared statement	283

Page

Hinkle, Maureen Kuwano, director, agricultural policy, National Audubon Society 47
Prepared statement 244
Kellner, Stephen, vice president, legal affairs, Chemical Specialties Manufacturers Association 35
Prepared statement 151
Maslyn, Mark, assistant director, national affairs division, American Farm Bureau Federation 74
Prepared statement 328
Miller, Richard, executive vice president, Prentiss Drug and Chemical Co., and chairman, legislative committee, Chemical Producers and Distributors Association 44
Prepared statement 234
O'Donnell, Patrick J., general manager, National Grape Cooperative Association, Inc., on behalf of the National Council of Farmer Cooperatives 80
Prepared statement 360
Stickle, Warren E., president, Chemical Producers and Distributors Association 40
Prepared statement 175
Tsongas, Paul E., former U.S. Senator, on behalf of the Humane Society of the United States and the Massachusetts Society for the Prevention of Cruelty to Animals 31
Prepared statement 137
Vroom, Jay J., executive vice president, National Agricultural Chemicals Association 17
Prepared statement 103
Wyckoff, Reggie, president, National Association of Wheat Growers 76
Prepared statement 341
Zedd, Sherri G., vice president, congressional relations, American Wood Preservers Institute 98
Prepared statement 381

SUBMITTED MATERIAL

Alabama Farmers Federation, American Feed Industry Association, American Oat Association, American Society of Farm Managers and Rural Appraisers, American Soybean Association, American Sugarbeet Growers Association, American Sugar Cane League, Beet Sugar Development Foundation, Florida Sugar Cane League, Georgia Peanut Commission, Hawaiian Sugar Planters Association, National-American Wholesale Grocers' Association, National Association of Wheat Growers, National Barley Growers Association, National Cattlemen's Association, National Corn Growers Association, National Cotton Council, National Council of Farmer Cooperatives, National Food Processors Association, National Grain and Feed Association, National Grain Trade Council, National Grange, National Milk Producers Federation, National Pork Producers Council, National Sunflower Association, North American Export Grain Association, Oregonians for Food and Shelter, Rio Grande Valley Sugar Growers, Rice Millers' Association, United Egg Association, United Egg Producers, U.S. Rice Producers Legislative Group, and Women Involved in Farm Economics, letter of October 18, 1989 27
Borman, Earle K., senior vice president, Lehn & Fink Products Group, statement 387
Hathaway, Janet S., senior project attorney, Natural Resources Defense Council, statement 392
James, Allen, president, International Sanitary Supply Association, statement 421
National Audubon Society, article by Jon R. Luoma 428

TUESDAY, OCTOBER 31, 1989

Brown, Hon. George E., Jr., a Representative in Congress from the State of California, opening statement 531
Roberts, Hon. Pat, a Representative in Congress from the State of Kansas, opening statement 542

WITNESSES

	Page
Fisher, Linda J., Assistant Administrator, Office of Pesticides, and Toxic Substances, U.S. Environmental Protection Agency	547
Prepared statement	579
Parnell, Jack C., Deputy Secretary, U.S. Department of Agriculture	544
Prepared statement	579
Synar, Hon. Mike, a Representative in Congress from the State of Oklahoma	532
Prepared statement	577

a 120-year-old brand that we have a responsibility to protect. We take that very seriously.

On the production side of this, we feel that current times demand that we be able to ascertain immediately what the impact might be if a registered chemical were proposed to be withdrawn from use by our members. We need to understand the economic impact, be aware of what the alternative might be, in order that we can properly manage the business.

Mr. BROWN. Well, this subject has risen to a very high priority very quickly because it's clearly related to both food quality and ground water, maybe not exactly in the way that some people think, but that data becomes an important piece of information for making policy as to what steps are needed in both these areas. These are very high priority areas.

Thank you very much, all of you. I concur with what Mr. Olin said. Your testimony has been extremely good and helpful to the committee, and we appreciate it. Thank you.

Mr. BROWN. Next, we are privileged to hear from the distinguished Dr. Charles Benbrook, Executive Director of the Board on Agriculture at the National Academy of Sciences. We hope that those flattering words will get him a pay raise.

STATEMENT OF CHARLES M. BENBROOK, EXECUTIVE DIRECTOR, BOARD ON AGRICULTURE, NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES

Mr. BENBROOK. Thank you, Mr. Chairman. It's a pleasure to be back here again.

I would like to first just lend my voice of thanks to the subcommittee for holding the joint hearing with the Senate on Tuesday on our new agricultural research initiative.

Mr. Chairman, I have a fairly lengthy prepared statement which reminds the committee of the principal findings, conclusions, and recommendations of our 1987 report. I'd ask that that be included in the record.

Mr. BROWN. Without objection, it will be a part of the record.

Mr. BENBROOK. I had an opportunity to speak briefly with Mr. Roberts yesterday, and he asked that I devote my attention this afternoon, to the extent that I can, to an assessment of the two pieces of legislation before the subcommittee and offer what observations and recommendations I might be able to make on how a piece of legislation fully responsive to the recommendations of our report might be crafted out of these two pieces.

First of all, having the responsibility to speak from at least a modest understanding of these two bills required me to spend more time studying both your earlier piece of legislation, H.R. 3153, as well as the new committee bill H.R. 3292. I'm very pleased to say that I find in them a number of very innovative and I think constructive provisions which, if creatively knitted together, will go a long way toward resolving the problems that face the country.

I'd like to walk through H.R. 3153, and if you have a copy of the printed bill in front of you, it might make my comments somewhat more understandable.

The principal provision in H.R. 3153, Mr. Brown, is, as you know, the change in the cancellation process. In the standard for consideration of a cancellation, I think that the basic standard is stated in a somewhat clearer fashion and one which the EPA will have an easier time of sustaining. So to an extent, I think that alone will facilitate the process.

I also think the language on page 3 that makes it very clear that proponents of a registration bear the burden of proof in showing that the standard for a cancellation is not met is appropriate to include in the statute. This is consistent with the most recent court interpretation of the existing law, but it is appropriate to put it into statutory language.

Further, in the amendment, in this cancellation provision in your bill, Mr. Chairman, you require that one of the factors that's taken into account is the impact of the cancellation order on retail food prices. The committee bill also has language related to benefits that would require a similar analysis, and I would simply note—and I will be discussing this in more detail later—that there are a number of factors that affect the price of a raw agricultural commodity as it moves through the retail food chain, and that the committee needs to be very thoughtful in assessing what issues will be taken into account. I think that in general you will find that any change in the availability of a pesticide, unless there are absolutely no other control alternatives, will in the end have a very modest impact on retail food prices and will, in most cases, yield little useful information.

There is another provision in this bill, Mr. Chairman, on page 5, subclause 4, the top of the page, that requires the Administrator to include in the cancellation order any possible changes in the registration that would be necessary and successful in bringing the risk from continued use of the pesticide to an acceptable level. It's sort of requiring EPA to determine if there is some change in use patterns, formulations, application rates, timing of application, that would reduce the risk such that the benefits would not exceed the risks.

There is, incidentally, a similar provision in the committee bill which I'll note later. This provision, Mr. Chairman, while one can see a logical reason for it, it really places a very significant analytical burden on the agency to try to come up with an assessment how any number of changes in use pattern might result in reductions of risk. Well, without an opportunity to go out into the field and try a new formulation or reduce the application rate or lower the number of applications, the EPA will not have a solid basis for making these determinations. And registrants could then petition or challenge in a court of law the cancellation order on the grounds that all the options to reduce risks have not been thoroughly explored by the EPA. As a result, this provision might, in fact, slow down the process quite considerably.

The judicial review provisions in H.R. 3153, Mr. Chairman, I find to be very straightforward, and I think that they will prove to be a positive model that the subcommittee should look at in however you craft together a cancellation by rulemaking or the cancellation provisions in H.R. 3153.

28-896 O - 91 -- 4

On page 22 of H.R. 3153, Mr. Chairman, there is a very significant provision which I would urge the subcommittee to study thoroughly because it would have a profound impact, I think, on the overall effectiveness of the FIFRA statute in bringing about a steadily improving balance in the risks and benefits of pesticides. The provision is very simple. It's a sunset provision. It says that a pesticide, once it is registered or reregistered, is done so for a 9-year period. At the end of that period, the registrants, if they wish to have the pesticide remain on the market, will have to come in and basically, as if it were a new product, meet the current risk-benefit standard and the current scientific and toxicological principles and criteria that the EPA applies to any new product.

This is a very important provision, Mr. Chairman, because it eliminates the fundamental bias against new chemicals that exist with current law. And this provision will take a great deal of pressure off the cancellation and suspension process because it will require every 9 years each product to come in, in a de novo fashion, and meet the standards for risks and benefits. The only time the cancellation provisions would then come into play would be in the event of a new study or unexpected finding during the pendency of a 9-year registration period, which causes EPA to elevate up the risks associated with the pesticide or, for some reason, substantially reduce the benefits assessment. I think that would impact substantially fewer chemicals.

I'd like to direct your attention to page 30, Mr. Chairman, in the provisions for use of suspended pesticides. This is a very innovative provision, Mr. Chairman, and I think it really deserves careful study. I'd like to note quickly that this provision could very readily be incorporated into the committee bill and would provide EPA with the same beneficial mechanism to allow a way for use of the pesticide to continue in a State where, for reasons of climate or pest pressure or whatever, the pesticide can continue to be used without posing risks above a negligible level, rendering significant benefits to both growers in the State and the public and not posing any risks.

What this provision would do is allow EPA to proceed with a national or Federal cancellation and suspension action which would affect use of the pesticide, presumably in those areas where risks do exceed benefits, but provide a way for the pesticide to continue to be used in areas where risks are very much lower than they are in other parts of the country.

If there's interest, I could give you two examples of how this would work, referring to some recent pesticide regulatory actions.

I also appluad you, Mr. Chairman, for identifying the conditions for which one of these 24(c) continued use registrations would be granted, such things as the conditions of use, the volume, whether the pesticide fits in with an integrated pest management program. I would urge you to consider adding as additional criteria for EPA to consider whether the pesticide is necessary in proven biocontrol programs and whether it could play an important role in managing the emergence of pesticide resistance.

I know, Mr. Chairman, you're aware of the continuing problem of resistance in many of the specialty crops grown in your State, and one of the great fears in production agriculture around the

country is that this current pressure to deal with food safety is going to result over the next few years in the loss of many, many products, particularly on minor use crops. And what could happen is that the entire pest control challenge could be vested on a few remaining products for some major pests, and that is a prescription for disaster because of the likelihood that in many cases genetic resistance to the remaining pesticides will evolve in 1 year or 2, and there will simply be nothing left.

I also note, Mr. Chairman, that you include a provision that directs the Administrator to assess benefits and work out a common procedure with the Department of Agriculture on how benefits should be calculated.

Turning to the committee bill H.R. 3292. I'll offer the following observations: On page 3 of the bill, where the basis for the rule—this is in the cancellation by rulemaking provisions—provisions starting on line 10 requires that the Scientific Advisory Panel be given an opportunity to review the evidentiary basis for the initiation of a special review, basically to review the validated tests or other significant evidence, and that the Scientific Advisory Panel should provide written recommendations to the Administrator as to whether the test or evidence reviewed satisfies the criteria under paragraph 1 for initiating a rulemaking under paragraph 1.

I'd suggest that the subcommittee reconsider this provision because what it basically is requiring the Scientific Advisory Panel to do is make a judgment of whether the risks exceed the benefits, because that's the only criteria in paragraph 1. So I think that while there may be a reasonable case to have the Scientific Advisory Panel assess the particular study or basis for initiating a special review, it certainly is not appropriate at the initiation of the process to require the Scientific Advisory Panel to render a judgment that can only be made at the end of the process.

Mr. ROBERTS. Excuse me, Dr. Benbrook. I think we're talking about a scientific peer review committee as opposed to the Scientific Advisory Panel.

Mr. BENBROOK. I'm sorry. But the same point would apply. This scientific peer review committee would be——

Mr. ROBERTS. It would be an in-house.

Mr. BENBROOK. An in-house committee?

Mr. ROBERTS. Yes, it's something we've been talking about with EPA which has not been established, but something we have been talking about with EPA already.

Mr. BENBROOK. I see the difference there. But, still, the criteria that need to be specified in that first paragraph is one other than whether the risks exceed the benefits, because that's the judgment that needs to be made at the end of the process.

Turning to page 11 of H.R. 3292, lines 18 and on down relate to the conditions when an issue of fact would be referred to the Scientific Advisory Panel for review. The bill reads that, "If any person submits comments under paragraph 6 in opposition to the proposed rule, the Administrator shall request the comments, evaluations, and recommendations of the Panel as to the impact on the health of the environment of the proposed rule," et cetera, et cetera. I would suggest that the subcommittee consider a more even-handed referral rule under which any comments that support the cancella-

tion order or raise questions about its validity be referred to the Scientific Advisory Panel.

The provision on page 12 on final action, this is the provision that relates to what I noted earlier in H.R. 3153, lines 10 through 15, "The Administrator may not prohibit use of a pesticide if alternative requirements will assure that the pesticide, when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment."

The Administrator is not going to have any factual basis to make this judgment on the impact of the change in use pattern until there's been an opportunity to have a growing season or two to go out and try it and make the test. So final action under this rule could kind of get caught in sort of an endless feedback loop where the registrants or user groups petition EPA to allow a change in use pattern, and then a season has to be allowed to occur so that a test can be made to see whether this alternative requirement brings risk down below a negligible level. Then the 2d year, perhaps a change in formulation could be tried. So there needs to be a consideration of how the Administrator would make a judgment on whether these alternative requirements would bring——

Mr. ROBERTS. If I could ask, Dr. Benbrook, he has that authority now, and he does it now.

Mr. BENBROOK. Pardon me?

Mr. ROBERTS. He has the authority now and he does it now in terms of what is going on today.

Mr. BENBROOK. Right.

Mr. ROBERTS. So if he does it now, I think he ought to have the authority, whether or not he has the backup or wherewithal or facts on down the road. I don't understand. And I apologize to my colleagues. We're in markup of the bill now, and I'll have an amendment in just a moment.

I'm sorry, Doctor. Go ahead.

Mr. BENBROOK. That's all right.

Another suggestion to make it clear that the provisions of this bill are going to facilitate movement toward the recommendations in our 1987 report, on page 18 it might be useful to add—this addresses what will happen in the review of tolerances—language that simply states that in reassessing and adjusting tolerances that they be set at a level defined as negligible. Then later on in this bill there is that definition in the Food, Drug, and Cosmetic Act provisions. This would simply make it very clear that there is a conformance between the FIFRA provisions and the Food, Drug, and Cosmetic Act provisions.

I commend the committee for including the pesticide-use data collection provisions, which appear in section 201 on page 25. I think that this authorization of $8 million, if appropriated, would constitute an enormous increase in our ability to develop pesticide-use records, and if the Government were to invest this kind of money in pesticide recordkeeping, Mr. Stenholm, I would suggest that it would substantially alleviate the burden on farmers to do so.

The State of California already requires and keeps very good records of all restricted use applications, and so almost none of this

money would need to be spent in California, since California is already doing that under State law.

So I just would alert the subcommittee to consider the interaction between this data collection provision, if it is maintained in whatever bill is passed and any recordkeeping provisions considered as part of this or other bills.

Mr. ROBERTS. Dr. Benbrook—and this isn't meant to be sarcastic—the thought occurred to me, we have been having a discussion up here on who gets this recordkeeping—who gets all the paperwork?

We thought about ASCS, the Soil Conservation Service, the EPA, and the Extension, and the FDA, which I guess would have the legal authority. I am wondering if you would like to have it.

Mr. BENBROOK. No, thanks.

Mr. ROBERTS. At the academy. We could build you a large repository.

Mr. BENBROOK. No, thanks. I appreciate the thought, though.

The very important provisions in the committee bill, title V, amending the Food, Drug, and Cosmetic Act, these provisions go right to the heart of the basic recommendation in our report, to bring about a consistent negligible risk standard for the purposes of setting tolerances for pesticides.

I have reviewed the provision fairly carefully, and I think that it basically will do what's needed. It is very important for legal experts, well versed in the nuances of the Food, Drug, and Cosmetic Act, to survey these provisions; but in general, I think that it will get the job done.

The one or two questions in these provisions that I would direct the subcommittee's attention to, on page 37 in clause (D), this language— ". . . if the dietary risk posed to food consumers by such level of the pesticide chemical residue is negligible, the Administrator shall by regulation set forth the factors and methods for determining whether such a risk is negligible."

I would urge the subcommittee to be a little bit more explicit in this requirement, and direct the Administrator to estimate exposure from a registered use of a pesticide, in the same fashion recommended in our committee report, which is to estimate the total exposure to the pesticide, based on the use of a pesticide on a single crop.

What this means is that you have to add together the exposure to pesticide X from any raw portion of the crop consumed as fresh foods, plus any processed foods derived from the crop.

It is entirely possible that in implementing this provision that's how EPA would, in fact, interpret it, but I think that it would be useful and constructive to simply require that they do so.

There are some questions that could be raised about the provisions that relate to establishing a tolerance level above the level deemed as negligible. The bill specifies on pages 37 and 38, three criteria which the EPA could cite in establishing or leaving a tolerance above the level that would be associated with a negligible risk.

Those three criteria, basically, are other hazards that are more serious than the dietary risk associated with the pesticide; the so-called risk switching phenomenon, where a regulatory action taken

because of dietary purposes, would increase use of another pesticide that might pose a ground water hazard or wildlife hazard; and then a sort of generic diet, health, consumer provision.

Again, I would simply point out that, while these considerations are very valid and logical questions in assessing the benefits of a pesticide, I think that these provisions would compel the EPA to get out into some very murky scientific water, where there is really no agreed upon way to make these estimates, and to require this kind of analytical finding to be made before the regulatory process can proceed will certainly not expedite actions.

I understand your concern, Mr. Roberts, about these provisions, and I would suggest that one of the constructive things that could be done would be to have EPA, in consultation with the FDA and USDA, see if they can come up with some analytical methods and sources of data to apply those methods, to test whether these kinds of criteria could, in fact, be incorporated into the regulatory process without really slowing things down.

I think that if that assessment were made before the provisions were enacted into law, it might save some major problems.

I would merely note, on page 61 of the bill, the National Uniformity of Tolerances provision, led me to remember the long and heartfelt debate in this very room on the 24A amendments in 1981 and 1982. I think that the new language in this National Uniformity of Tolerances provision will certainly rekindle that debate, almost immediately, and I would merely note that the language as crafted appears to be intended to preempt the provisions of Proposition 65 in California, and will certainly become a matter of discussion in the new pesticide initiative that has been filed in the State of California.

I merely note that that debate will complicate the politics of moving this total package together. I am sure that comes as no surprise to anyone in the subcommittee.

And last I'd like to commend the subcommittee and the authors of the bill for including this final provision for increased authorization for the testing of residues on imported foodstuffs. The $12-million increase of the HHS budget for pesticide monitoring in imported foods I think constitutes about a 30- or 40-percent increase, and would clearly provide resources badly needed to get a handle on the residues in imported foods.

The most recent report on residues of the EBDC's makes it very clear that the levels of residues, and of violative residues, in imported foods is a matter that we have to remain concerned about. I think that, then, by going through these bills and selecting out provisions that appear to be responsive to the key needs of expediting this process and giving EPA some additional authority could result in a bill that would really get the job done and would, in all respects, be responsive to the recommendations in their 1987 report.

Thank you.

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

Mr. BROWN. Thank you very much, Dr. Benbrook. We have a rollcall on, which requires us to recess briefly. But if I perceive the situation correctly, one or two members may have a question or two. So if you could remain, we would appreciate it.

[Recess taken.]

Mr. BROWN. We will continue, and I apologize very much to the witnesses that have been inconvenienced by these two votes that we had.

Dr. Benbrook, I understand that you have had an exchange with Mr. Roberts and reached some meeting of the minds as to where you agree and disagree, is that correct?

Mr. BENBROOK. Mr. Roberts raised two questions that he would like me to address briefly now and provide some further thoughts. Should I briefly summarize those? Would that be appropriate?

Mr. BROWN. If you will do so, just so the record will reflect it.

Mr. BENBROOK. He raised some questions about the impact of the two bills before the subcommittee on the import of food that might contain pesticide residues, and asked that I direct my attention to the possibility that one consequence of the bills as drafted might be that foods imported from overseas could come into this country with residue levels that would be above what would be either allowed or possible under U.S. regulatory standards and current label restrictions.

The other issue that Mr. Roberts raised was a useful approach to directing the EPA to consider the prospect that the cancellation or suspension of a pesticide use would lead to a more serious threat to public health because of a higher level of a natural mold, pathogen, or toxin. The best example that I know of is in the case of corn insecticides. Late season insect damage to an ear of corn opens up the ear and allows the aflatoxin mold spore to get into the inside of the ear, where it grows and becomes a very serious health threat.

Another circumstance when this happens, of course, is in a major drought, as in 1989, when the drought causes the ears on the corn to open up, and again, the mold spore can get in. And I think that there may be some way to fashion some language that would direct EPA to consider the prospect for such trade-offs between synthetic hazards and those resulting from uses of pesticide.

Mr. BROWN. There is no harm in those little worms in the ear of corn, is it?

Mr. BENBROOK. Well, the only harm might be if it—they are certainly nutritious, and they are rarely hazardous in any way—but if they turn off people from eating fresh fruits and vegetables, that could have a negative impact in the long run on the health status of the population, because we all need to eat more fresh fruits and vegetables.

Mr. Brown. Let me just ask you one more question, and then we can excuse you, knowing that we have imposed on you. Looking at H.R. 3153 on page 2 and page 18, where there are some slight changes in language with regard to the standard for cancellation and for suspension, the change with regard to cancellation on page 2 is essentially the addition of the term "reasonable probability," that the pesticide causes unreasonable adverse effects on the environment when used in accordance with its labeling or in accordance with actual practice, and then on page 18 with regard to suspension—let's see——

Mr. BENBROOK. Line 12.

Mr. BROWN. Line 12, generally causes an unreasonably adverse effect on the environment. Now, we had a witness this morning

that felt that this additional language was an extreme deviation from present policy or practice. And I just wondered if you would comment on what you see is the effect of this and the impact.

Mr. BENBROOK. I certainly do not view it as an extreme deviation. I think the language is somewhat more direct, and I think the language would pose on the agency a somewhat less strict standard to move ahead with a cancellation action.

I think it is appropriate that the standard for cancellation to initiate the process, is being stated as reasonable probability, is appropriate, and that then the standard for the final order is "generally causes"—that is a somewhat firmer finding of risk, to move forward with a final suspension order. So I find that fairly straightforward. And I do not think it would have a substantial impact on agency action, although I think, because it is somewhat simpler and more direct, would probably facilitate the process.

Mr. BROWN. Well, let me thank you very much for your contribution and particularly for your willingness to continue to assist the members of the committee in effecting this legislation. And we undoubtedly will be calling on you again.

Mr. BENBROOK. We have only been at it for 9 years now, Mr. Chairman.

Mr. BROWN. I know.

The Chair would like to call the last—the Chair would like to call what is left of the last panel—and that is Ms. Sherri Zedd, vice president for congressional affairs of the American Wood Preservers Institute.

Ms. Zedd, we apologize to you, too, for a very long day. I hope you understand that we are not entirely in control of our time here.

You may proceed with your testimony.

STATEMENT OF SHERRI G. ZEDD, VICE PRESIDENT, CONGRESSIONAL RELATIONS, AMERICAN WOOD PRESERVERS INSTITUTE

Ms. ZEDD. Thank you. Mr. Chairman and members of the subcommittee, thank you for the opportunity to present the views of the American Wood Preservers Institute on H.R. 3292, to amend the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA.

I am Sherri Zedd, vice president for congressional relations of AWPI. AWPI is a national organization representing the wood preserving industry on Federal environmental regulations. Our members include manufacturers of wood preservatives, as well as wood treaters.

The wood preserving industry is the largest nonagricultural user of pesticides in the United States and therefore has a great deal of interest in FIFRA. The industry has also experienced a long-running—from 1978 to 1985—special review, formally called RPAR, which increased our familiarity with the statute.

AWPI understands that the introduction of H.R. 3292 is a proper response to questions that have been raised over the effectiveness of the FIFRA cancellation and suspension procedures. We commend Chairman de la Garza and the other members of the House Agriculture Committee for introducing this legislation and for

UNRAVELING DELANEY'S PARADOX: UNFINISHED BUSINESS

Invited Testimony by
Charles M. Benbrook, Ph.D.

Before the Subcommittee on
Department Operations, Research, and Foreign Agriculture
House Committee on Agriculture

Mr. Chairman, I appreciate the invitation to appear before the subcommittee this afternoon. I am Charles M. Benbrook, Executive Director of the Board on Agriculture, one of eight major units of the National Research Council. The Research Council is the operating arm of the three academies: the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Bills before the subcommittee today contain essential elements of reform needed to act upon the principal recommendations in our 1987 report Regulating Pesticides in Food: The Delaney Paradox. Events since the release of our report highlight the need to restore credibility to the federal pesticide regulatory process. The key step in doing so is reducing excess dietary risk from pesticides while retaining, to the degree possible, valuable agricultural uses. Before I comment specifically on these proposals, let me first review the significant events that have brought us here today.

In 1981 and 1982, newly appointed policy officials in the Environmental Protection Agency initiated a range of significant reforms in Agency enforcement procedures and regulatory policies. Within the pesticide program, the most controversial and significant changes in Agency policy dealt with the scientific and regulatory principles underlying the estimation and balancing of risks and benefits stemming from the use of cancer causing pesticides. The subcommittee's December 17, 1982 investigative report, "EPA Pesticide Regulatory Program Study" (Serial Number 97-NNNN), described in some detail the major problems facing the Agency, with special focus on long-standing weaknesses in the tolerance setting and risk assessment processes.

In late 1983 after further oversight activity, Chairman Brown wrote the newly appointed EPA Administrator, Dr. William Ruckelshaus a letter raising a series of questions regarding the statutory basis and scientific standards underlying the Agency's regulatory posture toward pesticides known to, or suspected of causing cancer. The Chairman's questions probed the Agency to describe its legal, administrative, and scientific interpretation of what appeared to be conflicting regulatory standards governing tolerance setting for oncogenic (potentially cancer causing) pesticides.

By the spring of 1984, the newly appointed Assistant Administrator for Pesticides and Toxic Substances, Dr. Jack Moore had recognized that Chairman Brown's letter raised complex and fundamental questions about how the Agency has and will in the future reconcile the sometimes conflicting standard for setting pesticide residue tolerance levels. He decided to commission the National Academy of Sciences/National Research Council to undertake a study to identify scientifically sound analytical principles and procedures upon which to base the tolerance-setting process, and to resolve, if possible, the Delaney Paradox that arises from the conflicting provisions of the Food, Drug, and Cosmetic Act (FDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

In May of 1987 the NRC released the result of this EPA-commissioned study, Regulating Pesticides in Food: The Delaney Paradox. Since the report's release, EPA has taken some important steps toward implementing the report's principal analytical recommendations; and it has proposed to act upon some of the report's major regulatory recommendations. The diversity of views reflected in recent lawsuits, petitions, and comments on EPA's proposals to administratively act upon the report's recommendations highlights the need for legislative reform as an essential step in resolving Delaney's Paradox. Providing a clear and unambiguous statutory mandate to EPA on how to proceed is an essential first step in restoring confidence in the government's ability to protect the public from potentially hazardous levels of pesticide residues in food.

In an attempt to provide such a mandate and resolve fundamental statutory problems, several pieces of legislation have now been introduced in the 101st Congress. Two are before the subcommittee today, H. R. 3153 which I will call the Brown bill, and H. R. 3292 which I will refer to as the committee bill.

This morning I would like to highlight the major findings, conclusions, and recommendations of our 1987 report; identify the extent to which the report's recommendations are addressed in the legislation currently before the subcommittee; and, highlight a few critical issues that might warrant further consideration by the subcommittee and the Congress as the legislative process proceeds.

Major Findings of the 1987 NRC Report

- There are about 8,500 separate tolerances covering a residue of a distinct pesticide used on a distinct food crop--for example, captan residues in grapes.

- There are about 2,500 raw food tolerances set under section 408 of the Food, Drug, and Cosmetic Act (FDCA) for 53 pesticides the Environmental Protection Agency (EPA) identified as of July 1986 as oncogens covering residues in raw agricultural commodities; there are 31 tolerances for residues of the same pesticides in processed foods set under section 409 of the FDCA. These 31

tolerances appear to violate the Delaney Clause prohibition on the establishment of section 409 tolerances for annual carcinogens. (Since the release of the report in 1987, EPA has increased to 66 the number of suspected oncogenic pesticides registered for use on food.)

- Many processed foods derived from raw agricultural commodities treated with a pesticide are not accompanied by a section 409 tolerance, and/or have not been assessed to determine whether residue levels concentrate during processing. Of the 809 processed foods for which one of 28 oncogens analyzed by the committee is registered, there are only 31 tolerances so stated above. These 31 appear to violate the Delaney Clause. If these 809 processed foods were fully tested to determine whether residues concentrate, many more instances of concentration would be identified, triggering the need for additional section 409 tolerances.

- Ten fungicides account for over half the estimated worst-case dietary cancer risk from residues on or in fresh food. Across all three major types of pesticides (herbicides, insecticides, fungicides), fresh foods account for about 80 percent of total worst-case risk, and processed foods about 20 percent. It is important to note that since the release of our report all food uses have been discontinued by the manufacturers for three of these fungicides--captafol, folpet, and zineb. In addition, over a hundred other uses of the EBDC fungicides are subject to a voluntary cancellation request by the registrants, and will be addressed by a soon-to-be announced final regulatory decision by EPA.

- Residues of a dozen or so pesticides in or on 15 or 20 crops accounted for at least 90 percent of the total estimated worst-case risk.

- EPA has applied the Delaney Clause only to newer pesticides, even though older pesticides (those first registered before 1978) account for well over 90 percent of total worst-case dietary risk.

- EPA cites the Delaney Clause as the reason for denying registration of new pesticides posing worst-case cancer risks on the order of 10^{-7} to 10^{-8}, even though these new products would provide farmers a clearly safer alternative pesticide posing risks one hundredfold or more below the risk levels associated with currently registered products. Because the Delaney Clause has prohibited registration of clearly safer pesticides, it has actually slowed progress toward a safer food supply. This is why we called our report "The Delaney Paradox."

- Consistent adherence to a 10^{-6} negligible risk standard--applied to new and old products, all types of pesticides, and to the combination of residues in raw and processed foods derived from the same crop--would eliminate the vast majority (more than 90 percent) of worst-case estimated oncogen risk from pesticides. To achieve this level of risk reduction, the study concluded that only about 32 percent of all tolerances covering use of oncogenic pesticides--or some 750 tolerances--would need to be revoked. To eliminate the remaining small share of risk, an additional 1,500 tolerances would have to be revoked. (The committee's analyses considered tolerance revocations as the only way to reduce dietary risk. In contrast, several bills before the Congress--notably Congressman Waxman's bill, H. R. 1725 and the committee bill--would allow or require tolerance reduction as a means to reduce risk. Under these bills it is possible that similar levels of risk reduction could be achieved if tolerances are lowered to a comparably defined negligible risk level.)

- Strict and immediate adherence to the zero-risk standard in the Delaney Clause would eliminate, at most under current agency practice, a little over half the current level of worst-case risk in the diet, through revocation of nearly 2,000 tolerances covering use of oncogenic pesticides on 38 different crops. A negligible risk standard--viewed by many as a weakening of the Delaney Clause--would actually provide EPA greater opportunity to remove considerably more risk, assuming such a standard is consistently adhered to. This finding lies at the heart of the "Delaney Paradox."

The NAS committee's reassessment of the pesticide program's current statutory basis, and regulatory procedures led to a series of recommendations, which have been discussed previously before this subcommittee. Nonetheless they bear repeating in order to foster an assessment of the degree to which legislation before the Congress responds to the report's key recommendations.

Recommendations of the 1987 NRC Report

Our four principal recommendations are:

- A consistent standard should be applied to all pesticide residues in raw and processed foods, to new and old pesticides, and to all types of pesticides.

- This consistent standard should be a negligible risk standard. A negligible risk standard, applied consistently, could dramatically reduce risk with modest reduction of the benefits from the use of pesticides.

- EPA should focus its energies on reducing risk from the most worrisome pesticides on the most consumed crops.

- EPA should develop and apply improved analytical tools and a systematic approach to assessing dietary risks from pesticides, to assure that regulatory actions actually reduce overall risk--of all sorts--after farmers switch to available alternative pesticides or non-chemical control practices.

Critical Questions Before the Congress and the Public

Several key statutory issues have emerged since the release of our 1987 report. These issues are addressed to varying degrees by H. R. 3153 and H.R. 3292, as well as in legislation drafted by Congressman Henry Waxman (H. R. 1725). The two central legislative issues that must be dealt with if EPA is to have a clear mandate on how to act upon our report's recommendations are:

- What standard should govern tolerance setting, and how should it be applied?

- How should the registrations and tolerances governing use of the several dozen old pesticides accounting for most of the potential risk in the diet be brought into compliance with the new regulatory standard?

Other important questions deal with the role of benefits in regulatory decisionmaking--when they should be considered and how they should be measured.

The Appropriate Standard and How to Apply It to Both New and Old Pesticides.

The effectiveness of any legislative reform will be determined, in large part, by how it defines and applies a negligible risk concept, at what level a negligible risk standard is set, and what EPA is required to do (and how fast and through what process) to reduce existing tolerances that currently could pose risks above a negligible level.

Pesticide residues in the diet are often the most worrisome result of a pesticide's use. In other cases, worker exposure, wildlife impacts, or groundwater contamination may be the Agency's greatest concern. If legislation or EPA actions tighten down too aggressively on dietary risks, many pesticide uses are likely to be canceled or abandoned by registrants, including some which pose rather marginal dietary risks. As a result, farmers will have to switch to other products or technologies, which may pose other, more serious risks. The loss of several hundred major uses of the 10 registered oncogenic fungicides could prove particularly disruptive,

and in the end counter-productive, since it is unclear how quickly farmers could adapt, how they might change pest control systems, or whether the public would face greatly elevated risks from natural molds, fungi, and toxicants which could become more difficult to keep in check.

Mr. Chairman, precipitous and aggressive regulatory action could also greatly accelerate the emergence of pest populations with genetic resistance to the few pesticides that remain on the market. While the public's concern remains affixed on dietary health risks, many scientists are deeply troubled by the rapid spread of resistance, and its long-run consequences for society and the environment. To combat growing problems with resistance Congress should seriously consider creating a prescription use category for certain pesticides for use in integrated pest management programs, as an alternative to allowing such products to be driven out of the farmers' arsenal by regulation or because companies are compelled to abandon the registrations in light of the costs inherent in the re-registration process.

Procedural Inconsistency With the FIFRA Statue

Our 1987 report addresses the need to eliminate inconsistency between the standard governing the setting of tolerances under FIFRA (risk-benefit) and section 409 (Delaney Clause zero-risk). The committee bill would resolve this inconsistency, the Brown bill would not--a significant oversight in the crafting of this particular bill. For all bills before the Congress, though--including Mr. Waxman's--important questions remain regarding the relationship between the FDCA tolerance standard and the process governing tolerance-setting and tolerance-adjustments, and the FIFRA registration provisions that determine what uses are allowed to go on a pesticide product label as well as the conditions of use. Labels are what govern lawful pesticide use, and are the critical link between farmers and applicators, and attainment of public health and environmental protection goals.

When scientific data points to possibly excessive risk, EPA has three basic options--cancel the use of the pesticide, change the way a pesticide may be used to reduce risks to a negligible or otherwise acceptable level, or the "collect more data but take no action" option. Label changes taken to reduce risks may involve restricting the number of applications, rates of application, or extending pre-harvest intervals. But even these changes must generally be made following and only at the conclusion of the time-consuming administrative procedures and in accordance with the risk-benefit standards in FIFRA.

Following the statutory requirements and procedures of FIFRA, EPA lacks authority as a means to reduce risk by lowering tolerances in an administratively expeditious fashion. One remedy to this situation, which the subcommittee might consider as an amendment to legislation before the subcommittee, is drafting a new section in the FIFRA statute providing EPA conditional risk reduction authority, patterned after the Agency's current

authority to grant conditional registrations. (Conditional registration authority allows EPA to grant a registration "conditionally," pending receipt of additional data. Congress granted EPA this authority in 1978 to lessen the time period needed to gain new product registrations.)

The need for conditional registration in the late 1970s is matched in the late 1980s by the need for conditional risk reduction authority, coupled with a more expeditious suspension/cancellation process as called for in the Brown bill. The suspension/cancellation provisions in the Brown bill warrant careful study, since they contain several intriguing ideas. The provision allowing a state to request a continuing registration under section 24(c) for a pesticide use otherwise subject to a federal (national) cancellation order is a particularly interesting proposal which could provide a mechanism to retain high-benefit low-risk pesticide uses in certain states where pest pressure or climate make it possible to use the pesticide without posing excessive risk. The subcommittee might consider highlighting compatibility with IPM, biological control systems, and pesticide resistance management as three key factors EPA must consider in deciding whether to approve such section 24(c) registrations, which might include a requirement "prescription use" for use with an approved IPM system. If the subcommittee chooses instead to pass the cancellation by rulemaking provisions in the committee bill, there is no reason why this novel concept in the Brown bill could not be incorporated into the committee bill.

The Role of Benefits and How to Calculate Them

Events in recent months highlight the difficult public policy issues that arise in the context of considering benefits in pesticide regulatory decisionmaking. One of the most significant provisions in the committee bill directs EPA to take benefits into account if a tolerance level needs to be set at a level which poses more than a negligible risk. While the bill provides needed guidance to EPA on how to define and measure benefits, it directs EPA into some murky scientific water. As currently written, it would compel EPA to estimate and compare risks from synthetic as opposed to natural carcinogens; and directs the Agency to weigh the health-promoting benefits from consumption of certain foods against the potential health risks stemming from pesticide residues on such foods. Mr. Chairman, while these are logical and important questions, it is important to evaluate whether EPA--or anyone--is prepared to answer these questions in a scientifically defensible manner given the current state of scientific knowledge. If the analytical challenges inherent in answering these questions prove formidable--as I predict they will--where will EPA get the resources, and can it afford the time to develop the answers? Don't forget to factor in additional time for SAP reviews and inevitable legal challenges. Then, the subcommittee must evaluate whether this new information will result in sufficiently improved decisions to justify the investment of resources and the unavoidable delay that will result in the regulatory decisionmaking process.

The 1987 NRC report did not speak directly to the complex issue of how to define benefits. If and when benefits are considered, many people argue that they should be defined more broadly. Ideally, the assessment of benefits should not stop at the farmgate, as is currently the case. In an ideal world where knowledge is free for the asking and undisputable, the net benefits of alternative pest control strategies--chemical and non-chemical--should be estimated and contrasted, taking into account the cost and availability of food, the ability to supply fresh fruits and vegetables year-round (a key factor in building consumer acceptance), the potential risks of pesticides and natural toxicants from food produced overseas or grown in this country without effective control measures, the cost of public and private efforts to assure and monitor the safety of the food supply (already several hundred million annually, growing fast with no end in sight), and the prospective direct medical care and lost productivity costs, as well as indirect costs in terms of human suffering, increased rates of birth defects and behavioral problems, etc. likely to result from continued use of pesticides (in manufacturing plants, on the farm, among farmworkers, people drinking contaminated water in certain farming regions, and the general public).

In more sharply defining the role for benefits in pesticide regulatory decisionmaking, Congress should assess realistically the cost and feasibility of carrying out benefits assessments. Given current risk assessment methodologies, it will be both contentious and costly to estimate pesticide use benefits in the way envisioned in the committee bill. Resources in both the public and private sectors are limited. Does it make sense to compel the private sector and government agencies to invest more heavily in estimating the benefits associated with the use of several old pesticides, or would the nation be better of in the long run to direct more effort toward developing and gaining wider adoption of proven biological control, Integrated Pest Management, and non-chemical pest control systems?

In sum, legislative proposals before the Congress share a common goal--restoring public confidence in the government's ability to act expeditiously and with due caution in assuring the safety of the food supply. To fully attain this goal, a combination of administrative and legislative reforms will be necessary. To date on the administrative front, many people believe EPA has moved about as far and about as fast as possible given the conflicting pressures and constraints it faces from lawsuits, petitions, and not incidentally, from the Congress itself. Regrettably, there is little reason to hope that EPA will be able to move quickly enough to restore public confidence or reconcile conflicting signals, until fundamental statutory contradictions are resolved and unless it is granted new authority and expedited procedures to take appropriate steps to reduce risks judged to exceed a negligible level. If one accepts this analysis, the Congress will eventually be compelled to act.

There is widespread concurrence among legal experts regarding how to resolve the conflicting standards in the FDCA governing tolerance setting. There is less agreement on how to apply the standard and what level it

should be set at. The most controversial issue remains essentially unchanged since the subcommittee began its pesticide oversight activities in 1981--what to do about the registrations of some 75 to 100 potentially hazardous pesticides first registered before 1970. The Brown bill deals with this issue by expediting the cancellation process and imposing a nine-year sunset provision. Legislation by Congressman Waxman proposes a three-year tolerance reduction process. The committee bill deals with this issue by proposing a new cancellation by rulemaking process, which may or may not prove more expeditious.

In my judgment, a thoughtful integration of the best ideas in these bills, augmented by a few additional provisions, would result in legislation fully responsive to the principal recommendations in our 1987 report, and would essentially unravel the gordian knot underlying Delaney's Paradox. The remaining steps in the legislature process are not likely to be easy since differing views remain about how far and how fast EPA should go in reducing risks. Nonetheless, I commend the subcommittee for scheduling this hearing, and hope you move ahead toward a markup as soon as possible.

Thank you for the opportunity to appear before the subcommittee this morning.