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EXTENSION OF FEDERAL INSECTICIDE,
FUNGICIDE, AND RODENTICIDE ACT

GOVERNMENT

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT
INVESTIGATIONS, OVERSIGHT, AND RESEARCH

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

ON

H.R. 7018

APRIL 15 AND MAY 1, 1980

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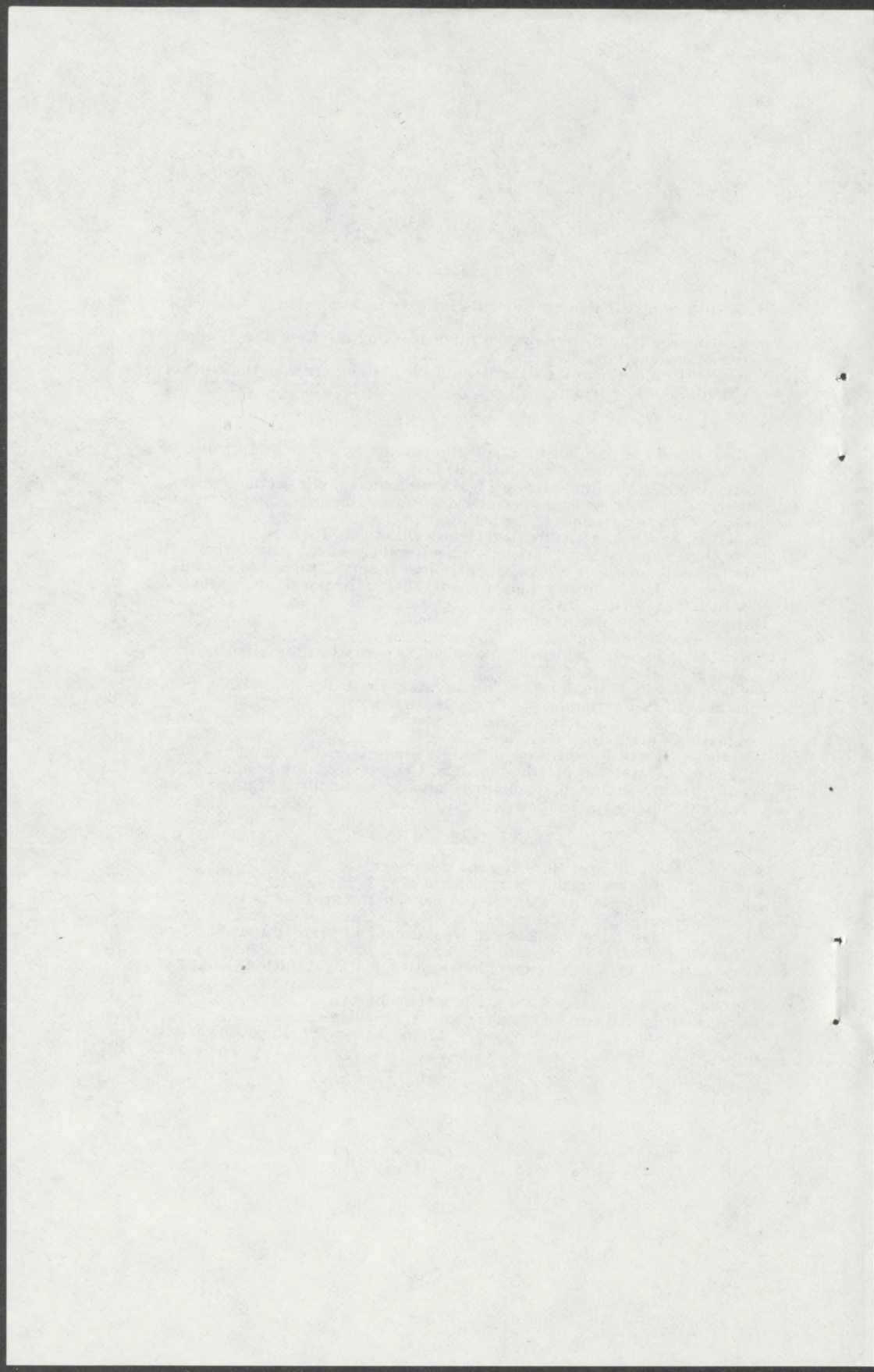
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EXTENSION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, APRIL 15, 1980

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT INVESTIGATIONS,
OVERSIGHT, AND RESEARCH OF THE
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m., in room 1302, Longworth House Office Building, Hon. E de la Garza (chairman of the subcommittee) presiding.

Present: Representatives Fithian, Skelton, and Wampler.

Staff present: Fowler C. West, staff director; Robert M. Bor, chief counsel; John E. Hogan, counsel; Robert T. Lowerre and J. Robert Franks, associate counsels; Glenda L. Temple and Peggy L. Pecore, clerks; Bert Pena, Thomas E. Adams, Jr., and Gerald R. Jorgensen.

OPENING REMARKS OF HON. E DE LA GARZA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. DE LA GARZA. The subcommittee will be in order.

Today the Subcommittee on Department Investigations, Oversight, and Research meets to receive testimony from public witnesses on H.R. 7018, a bill to extend the Federal Insecticide, Fungicide, and Rodenticide Act. This legislation if approved would authorize funding through September 30, 1981. Existing appropriations expire September 30, 1980.

H.R. 7018 authorizes to be appropriated such sums as may be necessary but not in excess of \$77,500,000. It also contains a sum of \$72,160,000 for the current fiscal year.

[The bill, H.R. 7018, follows:]

[H.R. 7018, 96th Congress, 2d session]

A BILL To extend the Federal Insecticide, Fungicide, and Rodenticide Act until September 30, 1981

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 31 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136y), is amended by adding at the end thereof the following: "There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1979, and ending September 30, 1980, such sums as may be necessary, but not in excess of \$72,160,000, and for the period beginning October 1, 1980, and ending September 30, 1981, such sums as may be necessary, but not in excess of \$77,500,000."

Mr. DE LA GARZA. Mr. Douglas Costle, the Administrator for EPA had a conflict and could not be with us for this hearing. Wanting to

have him testify, especially as head of the Agency, we have allowed the time for him to come on May 1.

We will expect him to respond to whatever questions or concerns, if any, are raised in the hearing today.

We welcome all of you back on May 1 to listen to Mr. Costle's testimony. The subcommittee, though, will not accept further testimony on May 1 from witnesses who testify today. However, if any questions are raised by members of the subcommittee, we hope that today's witnesses will be here to respond on May 1.

With that, we welcome all of you once again to what seems to be Mr. Wampler's and myself's career legislation. It is getting better because I think this is the longest authorization we have given this agency or will try to give them.

The witnesses this morning are Mr. Jack Early, National Agricultural Chemicals Association; Mr. Ralph Engle, Chemical Specialties Manufacturers Association. Are we working as a panel with Mr. Early, Mr. Reding, and Mr. Kellner?

Mr. EARLY. Yes, Mr. Chairman.

Mr. DE LA GARZA. Mr. Wampler?

OPENING REMARKS OF HON. WILLIAM C. WAMPLER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

Mr. WAMPLER. Mr. Chairman, we are taking up a bill today of peculiar simplicity. It is simple because it does two things. One, it authorizes funds to the Environmental Protection Agency to administer the Federal Insecticide, Fungicide, and Rodenticide Act as amended for 2 years. Second, it covers up a gross legislative error of the House.

Mr. Chairman, I cosponsored this bill because there is no way to go back and unravel the mistake that the House made last year in appropriating funds to keep FIFRA in place before the authorizing legislation had been approved. I hope this year that this committee does not give up its legislative prerogative and insist before the Rules Committee and on the floor that this bill be passed before the appropriations bill is allowed to come to a vote.

Mr. Chairman, I have no desire to drive EPA out of business as some perhaps believe. We need to regulate chemicals used in agriculture production and storage, and we also need to control the amount of hazardous chemicals that appear as residuals on foods. But, Mr. Chairman, we also need to keep a rein on the bureaucracy. I might add at this point that this committee and the House have gone on record time after time keeping this rein tight on EPA by just authorizing its funds on an annual basis. EPA has responded to this to a degree but not to the satisfaction of the majority of the House. The rein still needs to be held tight, and I believe the testimony will show that today.

Last year, Mr. Chairman, on April 24, to be exact, this subcommittee reported the bill H.R. 3546 authorizing funds for a simple extension of the FIFRA Act from October 1, 1979 to September 30, 1980. Later, the full Committee on Agriculture reported the bill amended to the floor on May 3, 1979. As amended, the bill would have authorized the temporary use of Mirex to combat the dreaded fire ant in a number of Southern States. It would have given to the Congress the veto over

EPA's FIFRA regulations and, finally, would have terminated the FIFRA Act by the so-called sunset provision in 1985.

The House passed H.R. 3546 after striking the Mirex provision on November 28, 1979, and on December 18, 1979 the Senate in conference balked on accepting the legislative veto on the sunset provision and the bill remains dead for all practical purposes in conference.

The Senate could afford to kill H.R. 3546 in conference because the House allowed the Appropriations Committee to go through the Rules Committee and vote on the EPA appropriations without an authorization.

We must insist, I think, Mr. Chairman, that this not happen again this year.

I have one other point, Mr. Chairman. I deeply regret that the Government witnesses are being scheduled out of turn. I understand their predicament, and I hope there is some way that can be found to allow the public and the industry representatives to answer questions or perhaps rebut the positions that will be taken by the administration after they testimony on May 1. Thank you.

Mr. DE LA GARZA. Thank you. Dr. Early, we will be very happy to hear from you and your panel at this time.

STATEMENT OF JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, ACCOMPANIED BY NICHOLAS REDING, GROUP VICE PRESIDENT, MONSANTO CO.; AND JOHN CONNER, GENERAL COUNSEL

Mr. EARLY. Thank you, Mr. Chairman.

I am Jack D. Early, president of the National Agricultural Chemicals Association, NACA. With me this morning on my right is Mr. Nicholas Reding, group vice president with the Monsanto Co. He also serves as chairman of our board of directors of NACA.

On my left is Mr. John Conner, our general counsel.

Mr. Chairman, the members of NACA, as I am sure you already are aware, produce a substantial portion of all the pesticides used in the United States for agricultural purposes—both the basic pest control chemicals and the end-use pesticides formulated from these basic chemicals.

Mr. Chairman, I would like to summarize our statement this morning and ask, with your permission, that the full statement be made a part of the record.

Mr. DE LA GARZA. Without objection, the full statement will appear in the record after your summary.

Mr. EARLY. Thank you, Mr. Chairman.

Mr. Chairman, we support H.R. 7018 to authorize a 1-year extension of the funding for the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

We would like to take this opportunity to report on the industry assessment of EPA's progress in implementing FIFRA and the 1978 amendments. We would also like to compliment the agency on a number of its accomplishments. There are several areas, however, where we believe that clarification and improvement will be required to address problems that are being experienced by our industry.

It is not our intention to seek, nor will we suggest, any specific legislative changes to FIFRA at this time. We are fully aware of the congressional desire to expedite the authorization of funding for the Agency, and to hold full oversight hearings at some later date.

NACA supports this approach and encourages the committee to undertake a full legislative review prior to any additional funding authorization of FIFRA for fiscal year 1982.

The issues which have arisen are complex and will require careful consideration by Congress before or during 1981. NACA will be prepared to make specific recommendations for any pertinent legislative changes at that time.

When I testified before this subcommittee on April 27, 1977, and again on April 24, 1979, I identified three particular areas of concern; namely, conditional registration, protection of trade secrets, and the consideration or use of test data to register pesticides produced by others. Although Congress did not fully adopt all of our suggestions, the industry has attempted to accept most of the changes in the law, but has reserved the right to comment on the implementation of the law by the Agency. In several areas, the administration of the law has proven inadequate to address industry's serious concern.

More specifically, I would like to mention some of these areas:

First, the cite-all regulations. The EPA is requiring applicants who have submitted all required test data to pay duplicate compensation for additional data of others not needed to support their registration.

Mr. Chairman, I should also point out that this is an area that is presently within the court and is being litigated by our association. We feel very strongly that the statute is quite clear in providing for a two-track system for a registrant to register his product with the Agency. That is, the registrant has the opportunity to supply the necessary data to meet the requirements, or he has the option or alternative to cite the existing data in the file. I am pleased to report that we are in a negotiation mood with EPA on this litigation, and it is our sincere hope that we can arrive at some outside settlement with EPA without having to pursue the court action.

Second is the protection of trade secrets. FIFRA authorizes disclosure of valuable proprietary research data, which are regarded by industry to contain trade secrets, to foreign and domestic competitors who are free to unfairly use the data in competition with the owners.

We expressed our concern in the last several years about this provision of FIFRA, Mr. Chairman, and the fact that we have some 20-odd members of our association that presently have litigation in various Federal district courts throughout the country is an indication of a number of members of our company who are unhappy with the way the statute is presently structured.

The third item is the registration standards. The EPA has significantly failed to implement the simplified registration procedures, and instead has proposed something in the neighborhood of a \$200 million, 15-year program which we believe will merely delay registration and infuse a morass of insoluble administrative problems in the registration program.

I am pleased to report at this time, though, that we have had a number of discussions with the personnel at EPA and more spe-

cifically with Mr. Costle. The results of this meeting has been that our technical registration experts have had an opportunity to sit down with EPA technical registration experts, and while we still have some basic points of disagreement, at least I think we have a clearer understanding of what one another's position is in this area.

We have encouraged this sort of continued dialogs, and it is our hope that we can have more of these in the future.

The fourth item of concern is the State registration requirements. States, such as California, are adopting independant registration standards, which are inconsistent with the Federal registration standards and threaten to completely undermine the uniform national requirements for pesticide registration.

Again, Mr. Chairman, this is an issue that we have had to resort to the courts in order to get clarification. Our association has filed litigation against the State of California for what we believe is a severe encroachment over interpretation of the State's rights to pursue an independent registration process along the lines of EPA, and even beyond what EPA is requiring through the registration process. This is a very critical issue that we believe Congress will have to address at some time in the future.

A fifth item is the reporting of additional data. EPA is attempting to hold registrants criminally liable for not reporting of additional data concerning any adverse effects of pesticides, including toxic effects already known to the Agency, while FIFRA requires the reporting only of additional factual information concerning unreasonable adverse effects.

Again, it is an issue that is in the courts. It will be resolved by the courts. We have had an opinion passed down by the courts. I must say that our industry is not completely happy with the decision rendered by the courts. I also understand that EPA was not very happy with the decision rendered by the courts. But, nonetheless, it is an issue that was before the courts. It is one that will need to be addressed, I believe, by the Congress at some time in the very near future.

The sixth item is the opportunity to avert an RPAR. EPA is contravening the plain mandate of the Congress that registrants be given an opportunity to avert issuance of an RPAR by submitting additional data or correcting or clarifying risks associated with the pesticide product.

The chairman will recall that in the last session on oversight on FIFRA that it was brought out by Congressman Grassley that the Administration should have a procedure set up whereby there would be some private communications between the registrant and the Environmental Protection Agency before the Agency moved into an RPAR structure thereby to allow the registrant to come in and discuss with the Agency privately those areas of misunderstanding, perhaps, or areas where data might be adequate.

Again, this is one area where we are concerned and feel it should be looked at by this committee and by the Congress.

The seventh issue is the district court jurisdiction over EPA. The Agency is attempting to emasculate the jurisdiction of the Federal district courts to review EPA action concerning pesticides.

You will find a more lengthy discussion of this area in our written testimony, Mr. Chairman.

Next is the Scientific Advisory Panel, Mr. Chairman. Although FIFRA requires EPA to solicit the recommendations of this independent panel, their effectiveness could be enhanced by greater opportunities for complete scientific reviews of all regulatory actions; for example, the recent cancellation proceedings.

Again, we would like to compliment the Congress for establishing the Scientific Advisory Panel which we believe has been a very effective tool for EPA. Our only concern is that EPA has not utilized such a prestigious scientific body as often or as much as they should have.

We share the concern of Congress and EPA to protect the human health and the environment, but we do not believe that the pesticide programs are being administered in such a way as to achieve that necessary protection. Both public health and proprietary rights of registrants are being sacrificed to unfeasible, unnecessary, and costly bureaucratic programs. Instead of implementing existing laws in a timely fashion, the Agency has unjustifiably delayed registration, re-registration, and the issuance of test data guidelines to the frustration of the industry and the public, in order to divert its resources to questionable new programs that will not be implemented for up to 15 years. We are hopeful that the increased dialog between EPA and NACA will lead to some improvement in pesticide programs. We certainly encourage and anticipate more dialog in that area. In the meantime, however, NACA is preparing recommendations that we hope you will consider in 1981 to get the Agency's programs back on track.

That concludes the summary of my statement, Mr. Chairman, and we will be delighted to respond to any questions you may have.

Mr. DE LA GARZA. Thank you very much, Dr. Early.

Without objection, we will now place your prepared statement in the record

[The prepared statement of Mr. Early follows:]

STATEMENT OF
DR. JACK D. EARLY, PRESIDENT
NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION
BEFORE THE
SUBCOMMITTEE ON DEPARTMENT INVESTIGATIONS,
OVERSIGHT, AND RESEARCH
OF THE
COMMITTEE ON AGRICULTURE
UNITED STATES HOUSE OF REPRESENTATIVES
APRIL 15, 1980

I am Jack D. Early, President of the National Agricultural Chemicals Association (NACA). The members of NACA produce a substantial portion of all the pesticides used in the United States for agricultural purposes -- both the basic pest control chemicals and the end-use pesticides formulated from these basic chemicals.

We support H.R. 7018 to authorize a one-year extension of funding for the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

We would like to take this opportunity to report on the industry assessment of EPA's progress in implementing FIFRA and the 1978 amendments. We would like also to compliment the Agency for a number of its accomplishments. There are several areas, however, where we believe that clarification and improvement will be required to address problems that are being experienced by the industry.

It is not our intention to seek, nor will we suggest, any specific legislative changes to FIFRA at this time. We are fully aware of the Congressional desire to expedite the authorization of funding for the Agency, and to hold full oversight hearings at a later date. NACA supports this approach and encourages the Committee to undertake a full legislative review prior to any additional funding authorization of FIFRA for FY 1982. The issues

which have arisen are complex and will require careful consideration by Congress before or during 1981. NACA will be prepared to make specific recommendations for any pertinent legislative changes at that time.

When I testified before this Subcommittee on April 27, 1977, and again on April 24, 1979, I identified three particular areas of concern; namely, conditional registration, protection of trade secrets, and consideration or use of test data to register pesticides produced by others. Although Congress did not fully adopt all of our suggestions, the industry has attempted to accept most of the changes in the law, but has reserved the right to comment on the implementation of the law by the Agency. In several areas, the administration of the law has proven inadequate to address industry's serious concerns. Specifically:

1. Cite-All Regulations, - The EPA is requiring applicants who have submitted all required test data to pay duplicate compensation for additional data of others not needed to support their registrations.
2. Protection of Trade Secrets - FIFRA authorizes disclosure of valuable proprietary research data, which are regarded by industry to contain trade secrets, to foreign and domestic competitors who are free to unfairly use the data in competition with the owners.
3. Registration Standards, - The EPA has significantly failed to implement "simplified" registration procedures, and instead has proposed a \$200 million, fifteen-year program which we believe will merely delay registration

and infuse a morass of insoluble administrative problems into the registration program.

4. State Registration Requirements. - States, such as California, are adopting independent registration standards, which are inconsistent with the federal registration standards and threaten to completely undermine the uniform national requirements for pesticide registration.

5. Reporting of Additional Data. - EPA is attempting to hold registrants criminally liable for not reporting of additional data concerning any adverse effects of pesticides, including toxic effects already known to the Agency, while FIFRA requires the reporting only of additional factual information concerning unreasonable adverse effects.

6. Opportunity to Avert RPAR. - EPA is contravening the plain mandate of the Congress that registrants be given an opportunity to avert issuance of an RPAR by submitting additional data or correcting or clarifying risks associated with a pesticide product.

7. District Court Jurisdiction over EPA. - The Agency is attempting to emasculate the jurisdiction of federal district courts to review EPA action concerning pesticides.

8. Scientific Advisory Panel - Although FIFRA requires EPA to solicit the recommendations of this independent Panel, their effectiveness could be enhanced by greater opportunities for complete scientific reviews of all regulatory actions; e.g., recent cancellation proceedings.

We share the concern of Congress and EPA to protect the human health and the environment, but we do not believe that the pesticide programs are being administered in such a way as to achieve that necessary protection. Both public health and proprietary rights of registrants are being sacrificed to unfeasible, unnecessary, and costly bureaucratic programs. Instead of implementing existing laws in a timely fashion, the Agency has unjustifiably delayed registration, reregistration, and the issuance of test data guidelines, to the frustration of the industry and the public, in order to divert its resources to questionable new programs that will not be implemented for up to fifteen years. We are hopeful that the increased dialogue between EPA and NACA will lead to some improvement in pesticide programs. In the meantime, NACA is preparing recommendations for your consideration in 1981 to get the Agency's programs back on track.

The EPA "Cite-All" Regulations Violate FIFRA

NACA is concerned with the legality of EPA's cite-all regulations, insofar as they require an applicant for registration to pay "duplicate" compensation for test data, even though the applicant has already paid for and submitted to the EPA all of the data required for registration. In this respect the EPA's cite-all regulations are economically wasteful, serve no useful purpose and clearly violate FIFRA.

NACA believes that, under § 3(c)(1)(D) of FIFRA, if an applicant submits data of its own which fully satisfy EPA data requirements, there is no basis for the EPA to compel the applicant to rely on any other company's data to support the applicant's

registration, or to require the applicant to pay compensation for use of any additional data. Nevertheless, the cite-all regulations require an applicant for registration to pay compensation for all other data in EPA files which pertain to the registered product, even if the applicant has submitted its own data. (40 C.F.R. § 162.9-3 and § 162.9-4.)

NACA has brought a lawsuit in the United States District Court for the District of Columbia challenging these regulations as exceeding the EPA's statutory authority, insofar as they require an applicant who has submitted complete data of its own to nevertheless pay compensation for other data in EPA files. Section 3(c)(1)(D) establishes a two-track system by which an applicant may satisfy the data requirements for registration. This section provides that an applicant may either file test data supporting his claims, or alternatively file a citation to data previously submitted by others or which appear in the public literature. Under this section, if an applicant chooses to file test data of his own, he is not required to cite data previously submitted by others or to pay for such data.

The purpose of § 3(c)(1)(D) was to enable applicants who do not have sufficient data of their own to "license" or rely upon the data of other companies. It was not the purpose of this section to compel an applicant who has submitted satisfactory data of his own to make additional, duplicative payments for data of others which he does not need to support his registration. To require such duplicative payments imposes senseless financial burdens on applicants without contributing to the public safety.

Recognition of § 3(c)(1)(D)'s two-track system will not in any way interfere with the ability of the EPA to make comprehensive assessments of the risks and benefits of pesticides based on all pertinent scientific data. Congress previously made it clear that in the course of assessing risks and benefits of pesticides, "all data either voluntarily submitted hereunder or required to be submitted by the Administrator may be used by the Administrator in making determinations of the adequacy of the test data submitted in connection with other applications." (See p. 72 of the Report of the Senate Committee on Agriculture, S. Rept. No. 92-838, Pt. II, 1972, attached as Appendix A.) While the Administrator is free to use data in this fashion in the course of making scientific decisions on pesticides, this does not trigger any requirement to pay compensation. As § 3(c)(1)(D) expressly provides, and as the Congress has stated, compensation is required to be paid only "as concerns use of such data in support of another application without permission of the originator of the test data." (Senate Agriculture Committee Report, supra, at p. 72).

The position which NACA is presenting here today is the same position that Congressman Grassley took in the House Agriculture Committee's review of the cite-all regulations last year. (See copy of the pertinent page from the Congressional Record, attached as Appendix B.)

NACA will be submitting to the EPA within the next few days a proposal for settling its lawsuit concerning the Agency's cite-all regulations. This proposal embodies the two central principles which we have discussed above:

1. That an applicant for registration may satisfy FIFRA's data requirements by the submission of its own data (or citation of data which it previously submitted), without incurring any obligation under § 3(c)(1)(D) to rely on, or pay compensation for, other persons' data; and

2. That all data either voluntarily submitted or required to be submitted by the Administrator may be used by the Administrator in making determinations of the adequacy of the test data submitted in connection with other applications, as long as they are not used to affirmatively support other applications.

Agreement by EPA to these two principles, which we think are incontestable in light of the plain language of § 3(c)(1)(D) and Congress' clear expression of intent, would serve to settle NACA's litigation without the need for any further legal proceedings. (We note that in at least one other lawsuit, additional aspects of the cite-all regulations have been challenged. NACA's lawsuit does not encompass any such additional issues, and NACA takes no position as to the legality of any other aspects of the cite-all regulations.) We are hopeful that the EPA will accept our proposal and that further litigation on this issue may come to a halt. In any event, we think this Committee should make clear for the record the correctness of the two-track system under § 3(c)(1)(D) which we have discussed in these comments.

Protection for Trade Secrets
in Current Law Is Inadequate

The pesticide industry is continuing to experience problems with the unsatisfactory provisions in existing law for the protection of trade secrets arising from research data. The 1972 FIFRA included in § 10 strong protection for the confidentiality of trade secret information; that is, information which, if disclosed to competitors, could damage the owner's competitive position. Throughout the Congress' consideration of the Federal Pesticide Act of 1978, NACA opposed the amendments to § 10 suggested by EPA which require the public disclosure of virtually all pesticide research data.

It was, and still is, NACA's position that pesticide research data can constitute extremely valuable trade secret commodities. They are useful not only to obtaining federal pesticide registration, but also for product development and improvement, for international competition in the many nations which have data requirements, and for a number of other important business purposes. The production of these research data requires a long-term commitment of vast amounts of money, skilled scientific personnel, and research facilities. These data are produced at great risk with no guarantee that the end-product of the research will not result in successful commercialization.

The consequences of the elimination of trade secret protection for research data in the 1978 amendments have been most unfortunate for everyone concerned. Disclosure and consequent misuse of trade secret research data is a severe disincentive to

continued research and innovation in this country. It destroys valuable private property and places it in the hands of foreign and domestic competitors who have contributed nothing at all to the production of the trade secrets. FIFRA contains no prohibition against publication or unauthorized use of research data by persons who lawfully obtain such information from EPA, and thus § 10(g) is completely ineffective in protecting registrants from disclosure to foreign competitors of test data which Congress recognizes to have proprietary value and which the industry has treated as trade secrets.

The limited compensation available under § 3(c)(1)(D) for some data does not even remotely approach the value of the trade secret research data which is destroyed by EPA through public disclosure. The fact is that EPA has not ordered a single penny of compensation to be paid since the enactment of § 3(c)(1)(D) eight years ago. The Federal Mediation and Conciliation Service has not yet even promulgated final procedures for resolution of compensation cases, let alone made any awards.

To remedy the clear injustice wrought by the 1978 law, approximately 20 companies have brought lawsuits to prevent the irreparable destruction of their trade secret research data by EPA. The first court to consider the question has issued an injunction barring EPA from disclosing such information submitted to EPA prior to enactment of the 1978 amendments on the ground that this government action raises substantial constitutional questions which must be resolved as to whether it deprives companies of their valuable property without just compensation and due process of law.

Regardless of how these cases are resolved in the courts, it is appropriate, if not essential, for the Congress to reconsider this question of the protection of proprietary test data. We believe that both the protection of trade secret research data, and the legitimate public interest in review of such data, can be accommodated in a manner that will reasonably satisfy all interests. NACA is preparing recommendations for legislative action to achieve these goals.

Registration Standards

In 1978, Congress instructed EPA to prescribe "simplified procedures" within nine months for the registration of pesticides. Although the Agency immediately attempted to develop some registration standards on existing chemicals, the process was delayed by indecision and poor planning. In an effort to get the process moving, EPA published a notice of proposed rulemaking in the Federal Register of December 26, 1979, which outlined a complicated plan for gathering all data concerning a pesticide chemical and subjecting each chemical, or groupings of chemicals, to Agency and public scrutiny, before reregistering the chemical.

The program is not simple! We have been told that it will take up to fifteen years to complete, at a cost of over \$200 million. Recently, the Comptroller General issued a report which criticized the Agency for failing to resolve basic policy and procedural issues. Only last month has EPA finally released a "sample" registration standard based on a currently registered pesticide. In reviewing the GAO report and the sample standard, NACA continues to express its concern that the original intent of Congress is not

being followed and that EPA is unnecessarily introducing administrative problems into the registration program.

It is our contention that the actual reregistration of pesticide active ingredients will require the collection of all data on that chemical, and the filling of data gaps to conform with § 3 requirements; all of which will result in a comprehensive data base for a registration standard on each active ingredient, and at the same time complete the registration process, as required by FIFRA. Instead, EPA is spending a considerable amount of time and energy in trying to set up a single set of procedures for resolving all problems which could conceivably be encountered, before it begins to collect and evaluate data. In addition, the Agency hopes that a system can be devised so that a single review of a data base on a chemical will answer all questions concerning the chemical's safety and effects.

We cannot believe that the EPA approach is totally realistic. The proposed procedures are far from being simplified, and are inconsistent with the concepts of exclusive use, compensation, and data submittal which Congress carefully reconstructed in 1978. As shown elsewhere in this statement, the industry has serious problems with other aspects of EPA's regulatory scheme and has taken steps to protect their legal rights. These matters must be resolved by either judicial or legislative remedy. However, in the meantime, there is no reason why EPA cannot proceed to reregister existing pesticides according to active ingredients as they were directed in 1972, 1975, and 1978.

State Registration Requirements Undermine
Uniform National Registration Standards

The question of the authority of states to impose independent registration requirements on a federally registered pesticide has arisen because of actions by the State of California.

Prior to 1972, FIFRA authorized the Federal Government to register and regulate only pesticides shipped in interstate commerce. The authority of the states to require independent parallel registration was acknowledged. Reasonable uniformity between state and federal requirements was maintained by federal-state cooperation.

In enacting the 1972 amended FIFRA, Congress greatly expanded the authority of the Federal Government. The 1972 law required for the first time that the EPA register all pesticides shipped in either interstate or intrastate commerce. It expanded the authority of the EPA to establish guidelines for data on human and environmental safety as a condition of registration. It authorized the EPA to register a pesticide for either general or restricted use.

It was the expectation of industry, and we believe of Congress, that this greatly expanded federal authority was intended to establish uniform national standards for the regulation of pesticides.

In both the 1972 statute and its legislative history, Congress dealt to some extent with the division between federal, state and local authority over the regulation of pesticides. Subsequent experience indicates that these provisions are inconclusive and ambiguous. They require a fresh look by Congress.

Section 24(a) authorized the states to "regulate the sale and use of pesticides." Section 24(b) denied to the states authority to require any labeling or packaging different from or in addition

to the federally registered labeling. Section 24(c) authorized the states to register federally registered pesticides to meet special local needs.

The legislative history of the 1972 amendments added somewhat to the statutory provisions. It specified that the state could not share its regulatory authority over pesticides with political subdivisions -- counties or municipalities. The House Report denied to a state the authority to impose use restrictions on a product which was federally registered for general use, but the prohibition was dropped in Conference.

Congress has further considered some of these provisions in the 1975 and 1978 amendments, but the ambiguity still remains.

The issue has now been clearly raised by the adoption by the State of California of regulations which in effect assert a total independence from EPA registration determinations. As a condition of state registration and tolerance determination, California asserts the authority not merely to require the submission of all research data which have been submitted to the EPA, but also to require massive amounts of research data in addition to that required by the EPA for registration. It has asserted the authority to make its own independent risk and safety assessment based upon these expanded data requirements.

Inherent in this assertion of authority is the power to deny California registration to federally registered pesticides, to impose state registration requirements different from federal standards. By adopting different registration standards, the

state necessarily comes into conflict with § 24(c), which prohibits states from adopting labeling different from or in addition to federally registered labeling. Because the federally approved label does not meet state requirements, the state will deny registration.

When Congress considered the amendments to § 24 in 1978, the Senate Committee on Agriculture, Nutrition, and Forestry stated in its report:

Federal registration has preempted State registration except for "special local needs." This is due to recognition of the need for national uniformity in arriving at degree of risk to which the public is exposed and the extent of showing which a registrant must make.

S. Rept. No. 95-334, 95th Cong., 1st Sess., p. 29 (1977).

We believe this statement clearly reflects the intention of Congress. If California, or any other state, has authority to completely disregard EPA registration and set its own independent registration standards, the registration of pesticides will be completely balkanized. There would be no national uniform standard. Congress would have done a useless thing in expanding in 1972 federal authority to register intrastate shipments of pesticides.

NACA and a number of its member companies have instituted litigation in the United States District Court in California to challenge the assertion of this authority by the State of California. That litigation is now pending. Regardless of the outcome of that litigation, NACA suggests that there is a compelling need for Congress to again review the division of authority between the federal and the state governments over the regulation of pesticides. The primary issue in such a review will be the authority of the

states to establish data and risk assessment standards different from those established by the EPA. There are numerous other areas of pesticide regulation where the states have a perfectly logical and recognized cooperative role to play with the Federal Government.

Reporting Requirements

In November 1977, NACA filed a lawsuit in the District of Columbia to challenge 1975 regulations implementing the unreasonable adverse effects reporting requirements in § 6(a)(2) of FIFRA. Although EPA subsequently revoked the regulations, the Administrator adopted an opinion of its Office of General Counsel that, in effect, reinstated the same interpretation of the provision. Recently, in February, the District Court issued an opinion which upholds the EPA's position, but excluded certain types of information from the reporting requirements. At best, the decision is confusing and the case may be appealed.

The problem with § 6(a)(2) is strictly a matter of interpretation. The industry has no problem with the wording of the provision, or with the fact that serious problems involving pesticide products should be brought to the immediate attention of the regulatory agency. But the industry sees no point in requiring companies to report any adverse effect which may already be known to the Agency, or may be expected to occur by the very nature of the chemical. The law clearly states that registrants are required to submit only additional "factual" data on "unreasonable" adverse effects of the pesticide. These qualifying terms are important limitations on the submittal of information from the flood of

reports, both confirmed and unconfirmed, which are received by each company in its routine day-to-day operations.

At one point in the litigation, both NACA and EPA sat down to work out a set of acceptable guidelines to eliminate confusion on the type of information being required. Unfortunately, negotiations broke down over a misunderstanding of whether the General Counsel opinion would be retained. While the talks were in progress, the parties were beginning to reach some compromises on important underlying issues.

NACA is still willing to attempt to work with EPA again to devise a satisfactory solution. Of possible consequence is the experience found in regard to the interpretation of § 8(e) of the Toxic Substances Control Act (TSCA) which is a similar reporting requirement. The 8(e) mechanism excludes trivial data and duplicative information, so that serious problems can be brought to the Agency's attention. It is evident to us that the enforcement of § 6(a)(2) could best be accomplished under a uniform policy incorporating both FIFRA and TSCA. While we take no position on the total acceptability of any such approach, Congress should address this issue. Otherwise, EPA will hold registrants criminally liable for failure to report data which are already known to the Agency, trivial or insignificant information, or data which are unreliable or invalid.

EPA Is Denying Registrants the
Opportunity to Avert Issuance of an RPAR

FIFRA § 3(c)(8) regarding "interim administrative review" or RPAR was added to the Act in 1978 as the so-called Grassley Amendment. In the Conference Committee Report (pp. 35-36) the

Administrator was specifically directed to afford registrants a private opportunity to avert issuance of an RPAR:

. . . the Administrator is directed to notify in writing the registrant of a pesticide product under special review of the exact scope and nature of any alleged unreasonable adverse effects to human health or the environment, prior to initiating an RPAR process. Such notification will be by private communication and afford the registrant a reasonable opportunity to correct or clarify through the submission of data any such risk associated with its pesticide product. This in turn could obviate the need for an RPAR to issue. This notification process will furnish a greater degree of protection for the property rights of pesticide registrants and ameliorate the indictment-like characteristics of the RPAR process.

The Agency has largely ignored the directive set forth in the Conference Report. Attempts by registrants to invoke the directive for the purpose of obtaining and reviewing in advance of an RPAR the data upon which the Agency plans to rely in support of the RPAR all have been unsuccessful. There still is no real opportunity for registrants to avert an RPAR by correcting or clarifying putatively adverse data before they are made public by EPA.

NACA suggests that in this Committee's consideration of FIFRA, the text of § 3(c)(8) be expanded to include the pre-RPAR notification procedure set forth in the Conference Report.

EPA Is Attempting to Restrict District
Court Jurisdiction to Review Agency Action

NACA believes it would be highly desirable to rewrite §§ 16(a) and 16(b) of FIFRA in order to delineate more precisely jurisdiction of the district courts and the courts of appeals to review EPA action. The EPA has attempted wherever possible to thwart any incisive district court review of its actions.

The legislative history underlying the 1972 amendments reflects a congressional intent to make the district courts the general repository of jurisdiction under FIFRA, and to vest the courts of appeals with jurisdiction only over a specific category of Agency actions; namely, "any order issued by the Administrator following a public hearing." The problem is that EPA has attempted to have as many cases as possible heard by the courts of appeals, rather than district courts, even when there is no real public hearing record for the appeals court to review. This frustrates the ability of courts and litigants to obtain meaningful judicial review of Agency action.

Scientific Advisory Panel

Since 1976, the Scientific Advisory Panel has held monthly public meetings to review and comment on all regulations and major regulatory actions contemplated by EPA. Although EPA has been responsive to comments and suggestions made by the Panel, the Agency has not solicited their input on all regulatory actions; e.g., recent cancellation proceedings.

The SAP represents the highest degree of technical expertise and competence in the scientific community, and has functioned as a model of objectivity. By allowing time for a full discussion of all aspects of topics under review, the SAP recommendations are being used to clarify testing requirements, and reduce the cost of registering a pesticide. Therefore, the Panel has had an economic impact on pesticide registrations; e.g., the Registration Guidelines, and could have an effect on other regulatory actions.

Conclusion

We appreciate the opportunity to address this Committee on our views concerning the implementation of pesticide regulations during the last year. We believe that there are a number of problems which Congress must address in the future, and we offer to submit specific legislative suggestions when requested at that time.

Excerpt from S. Rept. No. 92-838, Pt. II, 1972

72

TRADE SECRETS

LEGISLATIVE HISTORY RE TRADE SECRETS APPROVED BY LEN BICKWIT
SEPTEMBER 22, 1972, SUBJECT TO FINAL APPROVAL BY BERNIE NASH

(1) Information that constitutes a trade secret, financial information which is privileged or confidential, or commercial information the disclosure of which gives a competitor a competitive advantage with respect to the proprietor of the information should be protected from disclosure except under those circumstances enumerated in subsection (c) (1).

General approval is given to the definition of "trade secret" as incorporated in the RESTATEMENT OF TORTS.

In determining whether given matter constitutes a trade secret, consideration shall be given to—

- (a) the extent to which the data is independently known to outsiders or is used by outsiders for similar purposes;
- (b) the extent to which it is known by insiders;
- (c) the extent of the measures taken by an owner to guard its secrecy;
- (d) value of the data to the owner and others, including the extent to which, if used in conduct of a business, it would confer a competitive advantage on said owner;
- (e) the amount of effort or money expended in developing the data; and
- (f) the ease or difficulty with which the data could properly be acquired or duplicated by others.

Deliberation has been given to those circumstances under which it may be proper to release trade secrets. Those instances are set forth in subsection (c) of section 10. In all instances the disclosure shall be done in such a method as to guard the secrecy of the data as much as possible and insure it will not fall into the hands of a competitor.

Legislative intent with respect to section 3(c) (1) (D)

The change back to section 3(c) (1) (D) as reported by the Agriculture Committee with additions has essentially 2 purposes:

- (1) To authorize the Administrator to require a description of all relevant tests and their results and
- (2) To prevent unnecessary repetitive testing by subsequent applicants.

Thus, all data either voluntarily submitted hereunder or required to be submitted by the Administrator may be used by the Administrator in making determinations of the adequacy of the test data submitted in connection with other applications. As concerns use of such data in support of another application without permission of the originator of the test data, however, it is recognized that in certain circumstances it might be unfair or inequitable for government regulation to require a substantial testing expense to be borne by the first applicant, with subsequent applicants thereby gaining a free ride. On the other hand, unnecessary duplicative testing would represent a wasteful, time-consuming, and costly process resulting in a substantial misallocation of resources. Thus it was decided that fairness and equity require a sharing

of the governmentally required cost of producing the test data used in support of an application by an applicant other than the originator of such data. If no agreement can be reached, the Administrator is vested with authority to determine the reasonable share of the cost of the test data used, including subsequent reallocations upon requests for use of such data by additional applicants.

November 26, 1979

CONGRESSIONAL RECORD—HOUSE

APPENDIX B

H 11143

H.R. 3546 does not make any other changes in the basic charter for regulating the use and distribution of pesticides. Prior to 1978 there had been many problems encountered in administration of the act. The registration process was stalled and the act the subject of much controversy. As a result of extensive oversight by the committee, there was enacted last year a set of comprehensive amendments to FIFRA which I believe dealt with these problems in an even-handed manner. It is my belief that no additional program amendments are warranted at this time until the 1978 amendments can be fully and more accurately evaluated.

I hope the Members will join me in voting in support of the extension for 1 year of the funding authorization of FIFRA. Next year we will again review the administration of the act to determine whether any further changes are necessary.

□ 1240

Mr. GRASSLEY, Mr. Chairman, I yield myself such time as I may consume.

(Mr. GRASSLEY asked and was given permission to revise and extend his remarks.)

Mr. GRASSLEY, Mr. Chairman, I rise in support of H.R. 3546, to extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for 1 year, that is fiscal year 1980.

This legislation extends the authority for funding of Federal pesticide programs for 1 year through September 30, 1980. It provides for \$66,250,000 in funding authority. This legislation as originally reported by the Subcommittee on Department Investigations, Oversight, and Research provided for funding authority of \$62,250,000, but an amendment was adopted in full committee adding \$4 million to the amount currently budgeted to permit the Environmental Protection Agency (EPA) to share 50 percent of the costs incurred by the States in training and certifying pesticide applicators.

I should point out that the Public Law 96-103 providing appropriations for the Environmental Protection Agency for fiscal year 1980 has been signed into law. The law includes EPA funding for the pesticide program. Congress seems to have the cart before the horse here, for this is an important bill and it should receive House approval.

Three additional amendments were adopted by the full committee. The first of these provides for the temporary emergency use of Mirex, a pesticide to control fire ants, for the calendar years 1979 and 1980. The second amendment deals with the so-called one-House legislative veto which gives Congress the right to veto any future EPA regulations by adopting a resolution of disapproval within 90 congressional session days after promulgation by EPA. The third amendment, a sunset amendment, provides for the expiration of all provisions of FIFRA on September 30, 1985.

The American Farm Bureau endorses this bill as reported by the committee (see letter of October 9, 1979, which I ask unanimous consent to insert in the Record after my statement): "The

American Farm Bureau Federation urges your support of H.R. 3546 and its amendments as reported by the House Committee on Agriculture."

For some of the Members of the House, it may seem that an inordinate amount of time has been spent on FIFRA over the past few years. During the years 1977 and 1978, numerous hearings were held to try and resolve the conflicts that developed after enactment of the Federal Environmental Pesticide Control Act of 1972 and amendments thereto in 1975. The Federal Pesticide Act of 1978 was designed to cut the redtape in registration and re-registration of pesticides and resolve those issues that practically immobilized the Environmental Protection Agency pesticide program.

Only time will tell.

Deliberate action by the committee in the 1978 act extends the authorization for appropriations for only 1 year through September 30, 1979. For the very same reasoning—keeping this agency on a continuing oversight program—the Committee on Agriculture is recommending this legislation to extend authorization for appropriation only through September 30, 1980. The Environmental Protection Agency is, I believe, responding affirmatively to our committee's oversight activity, but the need continues to exercise effective oversight.

The additions by the committee of the "one-House" legislative veto of regulations and the sunset provision highlight a continuing concern by the committee members that our oversight responsibilities must continue to be actively pursued.

During the hearings held on this legislation, several witnesses indicated that problems were still being experienced with EPA's implementation of the 1978 amendments, but all agreed that an extension of 1 year might be helpful in allowing EPA additional time for implementation of the amendments passed last fall. The witnesses were assured that more extensive oversight hearings would be forthcoming if warranted, and industry concern with EPA's "cite-all" regulations relating to compensation for the use of data leave little doubt that hearings on fiscal year 1981 funding authorizations will address this issue.

In the latter instance I am referring to a problem which was raised at the hearings concerning the EPA's so-called cite-all regulations. The cite-all regulations are part of the newly published EPA regulations on compensation for use of data and appear at 40 C.F.R. sections 162.9-3 and 4—see 44 Fed. Reg. 27945, 27951. Where a generic standard exists for an active ingredient, the cite-all regulations require an applicant to acknowledge that his application relies on all data which, according to the generic standard, support the registrability of each use. Where no generic standard exists, an applicant is required to acknowledge that his application relies on all data in the EPA files which concern the applicant's product, or active ingredient, and are the type of data that EPA requires to be submitted for scientific review.

These regulations compel each applicant for registration to cite-all data in the EPA files which the EPA deems pertinent to the registration, and to offer to pay compensation under section 3(c) (1) (D) for all such data, even if the applicant chooses to rely solely on data that he himself has submitted which are sufficient to satisfy the EPA's data requirements for registration. Several district court cases have been filed which challenge these regulations on the ground that they exceed EPA's statutory authority.

As I have been led to understand the 1978 amendments, section 3(c) (1) (D) establishes a two-track system by which an applicant may satisfy the data requirements for registration. This section provides that an applicant may file either a full description of the tests made and the results thereof upon which his claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator.

Under this section, an applicant is not required to cite, or pay compensation for, data submitted by others if he chooses to rely on his own data, as long as his own data satisfy the requirements for registration established under section 3(c) (2) (A). To require applicants to pay for other persons' data when they have submitted satisfactory data of their own would impose needless financial burdens on applicants without contributing to the public safety.

Without the request of an applicant, the Administrator may consider any information in the EPA's files for the purpose of assessing the adequacy of the applicant's data, but the use of data in this manner should not trigger any obligation by the applicant to pay compensation for the data considered.

If the cite-all provisions of the 1978 enactment are not working as I have outlined above—and I understand they are not—then our committee should explore this issue when it considers EPA's fiscal year 1981 authorization for the pesticide programs.

Finally, several of my colleagues have expressed reservations over the Mirex and the legislative veto amendments. EPA has been working for over 2 years to find a pesticide to control fire ants but, frankly, it would appear that the efforts made are lacking in both funding and commitment. If we are told today that EPA has a viable alternative to fight fire ants, I will be pleased to know of this because fire ants themselves are a great health hazard.

The legislative (single House) veto you are all familiar with based on other legislation we have seen this amendment attached to in this session. The "sunset" amendment requires a reestablishment of the entire EPA pesticide enactment by October 1, 1985. If you support "sunset" provisions, as I do, I urge you to support this one.

I urge your favorable consideration of H.R. 3546 as reported by the committee.

Mr. Chairman, I attach the following letter:

H 11144

CONGRESSIONAL RECORD—HOUSE

November 26, 1979

AMERICAN FARM BUREAU FEDERATION,
Washington, D.C., October 9, 1978.
HON. WILLIAM C. WAMPLER,
U.S. House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN WAMPLER: The American Farm Bureau Federation urges your support of H.R. 3546 and its amendments as reported by the House Committee on Agriculture.

H.R. 3546 extends the federal pesticide law (Federal Insecticide, Fungicide, and Rodenticide Act) for one year. Additional provisions, added during committee consideration, provide an additional authorization of \$4,000,000 over the Administration's request in order to provide funds to meet cost-sharing commitments to the states for certification of applicator programs, register the pesticide Mirex for the calendar years 1979 and 1980 for fire ant control subject to limitations, provide for Congressional veto of EPA regulations and establish a sunset provision of September 30, 1985 for the pesticide program.

We particularly call to your attention the provision registering the pesticide Mirex. We recognize the Congressional registration of a pesticide is an extraordinary action, however, we are recommending it because of the failure of EPA to carry out the provisions in the law. Although Farm Bureau, by policy, advocates regulatory agency resolution of complex scientific questions, we believe this unusual action is justified because (1) EPA has been defaulting in its response to petitions for relief from the fire ant problem which have been pending unanswered for over a year; (2) the registration provided in the bill is subject to the extensive limitations on use that were in effect in October, 1977; and (3) the registration is of limited duration and is intended to provide public protection from the fire ant pending EPA registration of alternative controls.

We thank you for your consideration of our views on this important matter.

Sincerely,

VERNIE R. OLARSON,
Director, National Affairs.

□ 1250

MR. DE LA GARZA. Mr. Chairman, I yield 7 minutes to the gentleman from Georgia (Mr. MATHEIS).

(Mr. MATHEIS asked and was given permission to revise and extend his remarks.)

MR. MATHEIS. Mr. Chairman, I thank the distinguished gentleman from Texas for yielding me this time.

As the author of the three amendments alluded to by the gentleman from Iowa (Mr. GRASSLEY) in his presentation, I feel constrained to say a few words, even though I have a strong feeling that we are going to hear some debate on this matter later in the week when the time comes for consideration of the legislation under the 5-minute rule.

As I understand it, the distinguished chairman of the full Committee on Agriculture, the gentleman from Washington (Mr. FOLLY), is going to move to strike two of the amendments that were adopted by the full Committee on Agriculture. We are going to hear much debate, Mr. Chairman, later in the week, and I am referring to the amendment relating to the one-Etoute veto and also the so-called Mirex amendment.

Let me address very briefly, as the gentleman from Iowa (Mr. GRASSLEY) has done, the need for the Mirex amendment

and why the Committee on Agriculture, by a vote of 22 to 11, voted on May 3 to impose upon EPA the mandate that it allow the usage of Mirex.

Mr. Chairman, it was not with any degree of enthusiasm that I offered that amendment in committee, because I do not think that as a basic legislative policy we ought to attempt to mandate to the Environmental Protection Agency those insecticides or pesticides they should or should not use. However, in this particular instance the situation has become so critical, not only in my State but in eight other Southern States, that I simply felt, as do many other Members of this body, that we had no alternative but to attempt to say to the Environmental Protection Agency, "You must allow us to use Mirex until such time as some alternative or viable substitute is found."

Mr. Chairman, it was because of the feeling among many of us that we had no choice in the matter that this amendment was offered, and I think in this case the argument we were able to make in the Committee on Agriculture was one that persuaded the members of that committee that we should in fact take this approach.

I would caution all the Members of this House that the legislation we are talking about is not permanent. It does not allow the continuation of the usage of Mirex over an indefinite period of time. It is not infinite. It simply applies to calendar year 1980.

In essence, the amendment does say that Mirex could be used at the same strict environmentally acceptable levels under which it was used in 1977 through the years 1979 and 1980. But in truth 1979 is gone. The opportunity for the usage of Mirex has passed this year. The only opportunity we would have for aerial application of Mirex now, under the provisions of the Mathis amendment, would be in the spring and fall of 1980 if the House in its wisdom retains this amendment, and Mr. Chairman, I hope it does.

One of the arguments that has been brought forth by the distinguished gentleman from Texas (Mr. DE LA GARZA) and the distinguished gentleman from Washington (Mr. FOLLY), the chairman of the committee, is that this is not the way that we should approach this problem. They do concede that there is precedent for this approach, because in the 93d Congress there was similar legislation that was introduced to deal with a particular problem that existed in the northwestern part of the country.

The full Committee on Agriculture did in fact vote to create an exemption in that instance for the use of a specific chemical compound to relieve a specific problem that existed in a specific part of the country.

That is exactly what we are talking about here today.

Fortunately for our friends in the northwest, the need for that legislation in the other instance became moot because the Environmental Protection Agency backed off from its previous position and decided to allow the usage of that particular compound that the com-

mittee had earlier voted to recommend they be allowed to use. That is not the instance in this case.

However, the gentleman from Texas (Mr. DE LA GARZA) and the gentleman from Washington (Mr. FOLLY) and going to tell us when they offer that amendment that we ought to, at least in the Committee on Agriculture, follow the normal legislative procedure of having full hearings on this amendment in the form of a bill that I introduced earlier this year. I refer now to essentially the amendment that is contained in the legislation before us here. The gentleman from Texas and the gentleman from Washington cite the fact that 3 days of hearings were held in the 93d Congress.

Mr. Chairman, I would submit to the gentleman from Texas and to the other Members that in fact this legislation was reported from the full Committee on Agriculture on May 3. That was 6 months ago, and still not 1 day, not 1 hour, not 1 minute of hearings has been held by the committee relative to this matter. Ample time has presented itself. We have had an opportunity to have hearings.

The truth is that we must act now, and I suspect very strongly, Mr. Chairman, that we will have an opportunity to hear the arguments pro and con, not only on this amendment but on the other amendments by which the gentleman from Washington intends to strike language later on in the week.

I do not want to be redundant, and I do not want to burden the Members of this body with repetitiveness. I just think, Mr. Chairman, that this legislation is the best bill relative to the Environmental Protection Agency that has ever been brought to the floor of the House.

MR. GRASSLEY. Mr. Chairman, I yield 2 minutes to the gentleman from Alabama (Mr. DICKINSON).

(Mr. DICKINSON asked and was given permission to revise and extend his remarks.)

MR. DICKINSON. Mr. Chairman, I thank the gentleman for yielding.

I would first, Mr. Chairman, like to commend the gentleman from Georgia (Mr. MATHEIS) for the statement he just made. He has stated the case adequately, I believe, so that all the Members can understand it.

I intend to support H.R. 3546 as it was reported by the Committee on Agriculture and will oppose the amendment to delete the language added by the gentleman from Georgia in committee. His language will allow the limited use of the pesticide mirex for the control of fire ants in several Southeastern States.

Fire ants are more than a nuisance in the Southeast, Mr. Chairman; they are really a health hazard. I would certainly hope that all of our colleagues will carefully examine this problem and, because this affects only the Southeast, not dismiss it as a small problem. As evidence as to its severity, I am including with my remarks a copy of a letter I received from one of my constituents, Mr. Jimmy Carlisle of Montgomery, Ala. His comments reflect the feelings of my constituents on this very serious matter.

Mr. DE LA GARZA. Mr. Skelton?

Mr. SKELTON. Mr. Early, you will recall the bill we struggled with at length and finally passed, I think, in the last part of 1978.

The problems that you have with the present law and the actions of the EPA—how do they compare with the testimony that was given here by you and your colleagues regarding our prior bill? In other words, what improvements, if any, have they made since the implementation of the new law?

Mr. EARLY. Unfortunately, a number of the issues that we have raised here before are issues that we have been raising for a number of years. I should take this opportunity to point out that one of the provisions that we did see the last time that the statute was adjusted as a provision that allowed EPA to proceed with a conditional registration. In case you have forgotten about that conditional registration process, it allows the Administrator to register or reregister a product even though there may be some data gaps in the data that he has in his files.

So, that has been a very positive move on the part of the Agency, that is, to move ahead with that conditional registration area.

Mr. SKELTON. With that one exception you are back where you started from? Is that what you are telling us?

Mr. EARLY. We are not quite back where we started from, but we have not really made a lot of progress.

I may ask my counsel if we can come up with a suggestion or two.

Mr. SKELTON. It is very disappointing to hear that.

Mr. EARLY. It is disappointing to me to have to say that.

Mr. SKELTON. Thank you.

Mr. EARLY. Counsel does not point out something to me. I should have mentioned this because it is a very critical area. It is a difficult area for this committee to struggle with—that is the provision that was put into the statute which provided for an exclusive use period of data and the compensation provision the way it was structured. That was a significant improvement.

Mr. SKELTON. Is that working?

Mr. EARLY. The exclusivity is working. I don't think we have still had enough experience with the compensation issue to know whether it really is working or not.

Mr. SKELTON. Thank you.

Mr. EARLY. To my knowledge, I do not believe there has been a compensation settlement on any issue.

Mr. DE LA GARZA. Mr. Wampler?

Mr. WAMPLER. Dr. Early, I want to thank you and your associates for being here this morning and presenting us with your very comprehensive statement. I assure you I will review it carefully and in more detail as the opportunity presents itself.

Among other things, as noted on page 3 of your statement, item 8, you referred to the Scientific Advisory Panel. You felt that while FIFRA requires EPA to solicit the recommendations of this Panel, their effectiveness could perhaps be enhanced by greater opportunities for complete scientific reviews of all regulatory actions.

I do not know whether you are aware of it or not, but I have introduced a bill that provides for the creation of a National Science Council which would be an independent body that would make scientific

determinations on a variety of questions submitted to it under its jurisdiction, including FIFRA, so that we can take the scientific determination away from the regulators and put it in the hands of truly a scientific body that can make an objective determination without any preconceived bias, hopefully.

Do you have any thoughts on that concept of not only utilizing what we have in terms of the Scientific Advisory Panel today and EPA but a further expression of that concept to an independent scientific body to make these types of determinations?

Mr. EARLY. We are aware of the legislation that you have introduced there and the concept that you are proposing. I would say at the outset that we are very much in support of moving the scientific decisionmaking process or keeping it within the scientific body. We believe very strongly that this is the place for the scientific decisions to be made, that is, in the scientific arena.

This would allow the Agency to make a regulatory decision. But we have been concerned all along, as I am sure you have, that the Agency should not necessarily get into the scientific decisionmaking process. Particularly this is true when you get into such controversial issues as cancer and some of the areas that are hotly debated among the scientific community. We need to take in our society today the best and fullest advantage of the best minds that we can find to deal with, and to address these scientific issues. So, we support the concept that you are approaching in that. We certainly do.

Mr. WAMPLER. I have particular reference to EPA's actions on 2,4,5-T which I think was rather precipitous. If I understand and recall correctly, EPA consulted their Scientific Advisory Panel after the fact in this particular case of the cancellation of this herbicide and others.

It is my further understanding that there is a current hearing or procedure taking place that is probably going to cost the taxpayers of this country millions of dollars on this whole question of cancellation of 2,4,5-T. While I certainly am in no position to prejudge what the ultimate outcome would be, my guess is that we will be right back to point zero, and what concerns me is the bending of the intent of FIFRA in the cancellation proceeding relating to 2,4,5-T and the fact that this Congress is going to have to come to grips within the next fortnight or thereabouts on trying to adopt a budget resolution which hopefully is going to call for a balanced budget, and I just happen to feel that this is one instance where an agency of the Federal Government could better be spending its resources and in fact our tax dollars and that we carefully examine this action taken on 2,4,5-T. It is just another classic example where we are needlessly, in my judgment, spending dollars which could otherwise be spent on agricultural research, teaching, extension, and soil conservation—the very things that ought to be done rather than diverting them.

This is why I feel the need to find a better way to make these scientific determinations and take that away from the political arena, and from the regulatory arena and put it truly where we don't bend science, and that we get the best scientific determination on what a given situation is.

Mr. EARLY. We are very supportive of that concept, Mr. Wampler.

Mr. WAMPLER. I thank you.

Mr. DE LA GARZA. Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

I did not hear the first part of your testimony, but I had a chance to glance at it. I compliment you on its completeness.

Mr. Chairman, I will just explore one issue with Dr. Early, and perhaps later on we can have opportunities to explore this a bit more.

I am concerned about the duplication of efforts and the cost that goes into the present procedure of the cite-all requirements by the Agency. I have had a chance just now to read your section on that. We have talked to some other people on those problems, and so we have some familiarity with them.

I wonder if for our purposes you could provide us with some specific dollar figures for a given procedure or specific dollar figures for a company which you might represent actually get into in fulfilling those requirements. I tend to believe they are duplicative.

Mr. EARLY. We do not have that with us today, but we could give you some numbers on that and make that available to the committee. It may take us a few days to come up with some numbers, but I think we could.

Mr. FITHIAN. I would appreciate that. My staff is working with some people to try to see if we cannot come from both sides of this problem and reach an amicable decision.

I take it from your written testimony here that that is probably the motivation for the suit which NACA is pursuing.

Mr. EARLY. It is in the courts right now, yes.

I should point out again that the critical issue here—while I am not a lawyer, I think the language is very clear in the statute where it says that a registrant has two options. He can supply the necessary data to meet the requirements of the registration of his label of his product, or, alternatively, he may cite existing data in the files. I think it is very clear. So, the only thing that we are in the courts with EPA on is the right for a registrant to supply his own data to satisfy the registration requirements and not have to cite or pay for somebody else's data that he thinks he does not need.

I think it is basically that question.

Mr. FITHIAN. I would just say, Mr. Chairman, that I thought when we did the amendments a couple of years ago that we had addressed that with some clarity. I regret that it has not worked out that way. Hopefully, we can work that out.

Mr. DE LA GARZA. Thank you very much, Dr. Early. I appreciate the information which you and your panel bring us.

Mr. EARLY. Thank you, Mr. Chairman.

Mr. DE LA GARZA. The next witness is Mr. Ralph Engel, president, Chemical Specialties Manufacturers Association. He will be accompanied by Mr. Kellner.

Mr. Engel, you may proceed as you wish.

STATEMENT OF
RALPH ENGEL, PRESIDENT
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

MY NAME IS RALPH ENGEL, I AM PRESIDENT OF THE CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION (CSMA), HEADQUARTERED AT 1001 CONNECTICUT AVENUE, WASHINGTON, DC. I AM ACCOMPANIED TODAY BY MR. STEPHEN KELLNER, CSMA VICE PRESIDENT, LEGAL AFFAIRS. CSMA HAS A MEMBERSHIP OF NEARLY 450 FIRMS ENGAGED IN THE MANUFACTURE, FORMULATION, DISTRIBUTION AND SALE OF INSECTICIDES, DISINFECTANTS AND SANITIZERS, DETERGENTS AND CLEANING COMPOUNDS, TRANSPORTATION CHEMICALS, AND WAXES, POLISHES AND FLOOR FINISHES FOR HOUSEHOLD, INSTITUTIONAL AND INDUSTRIAL USES. A SIGNIFICANT NUMBER OF THESE PRODUCTS HAVE PESTICIDAL CLAIMS AND ARE, THEREFORE, SUBJECT TO EPA JURISDICTION PURSUANT TO THE REQUIREMENTS OF THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT AS AMENDED (FIFRA).

SPECIFICALLY, CSMA REPRESENTS THE NONAGRICULTURAL PESTICIDE INDUSTRY, INCLUDING DISINFECTANTS AND SANITIZERS, HOME, LAWN AND GARDEN INSECTICIDES AND A WIDE VARIETY OF OTHER PESTICIDES FOR HOME, INDUSTRIAL AND INSTITUTIONAL USE.

I. H.R.7018 AUTHORIZATION OF FIFRA

ON SEVERAL OCCASIONS IN THE PAST, CSMA HAS APPEARED BEFORE THIS COMMITTEE TO TESTIFY ON VARIOUS ASPECTS OF FIFRA AND PARTICULARLY IN THE DEVELOPMENT OF THE 1978 AMENDMENTS. OUR PURPOSE IN APPEARING BEFORE YOU TODAY, AMONG OTHERS, IS TO COMMENT UPON H.R.7018, A BILL WHICH WOULD EXTEND THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT UNTIL SEPTEMBER 30, 1981.

IN THE PAST, THIS COMMITTEE HAS BEEN PARTICULARLY SENSITIVE TO REQUESTS THAT AUTHORIZATION FOR THE AGENCY BE LIMITED TO A PERIOD OF ONE YEAR. THIS PERIOD ACTS TO ENSURE THAT CONTINUED PROGRESS IS MADE IN THE IMPLEMENTATION OF FIFRA AND FURTHER ACTS AS A MECHANISM BY WHICH THE REGULATED PARTIES AND THE AGENCY CAN MAKE THEIR VIEWS

KNOWN TO CONGRESS. WE URGE, THEREFORE, THAT THE COMMITTEE AUTHORIZE ONLY SUCH SUMS NECESSARY FOR A ONE-YEAR PERIOD. IN ADDITION, WE WANT TO CALL TO YOUR ATTENTION SOME OTHER ISSUES OF CONCERN.

II. DISTINCTION BETWEEN AGRICULTURAL AND NONAGRICULTURAL PESTICIDES

CSMA, AS YOU ARE AWARE, WAS INSTRUMENTAL IN BRINGING TO THE ATTENTION OF THIS COMMITTEE THE CONCERNS OF THE NONAGRICULTURAL PESTICIDE INDUSTRY. THIS COMMITTEE, AND INDEED CONGRESS, RESPONDED BY AMENDING §25(A)(1) OF FIFRA TO DIRECT THE ADMINISTRATOR TO PRESCRIBE REGULATIONS THAT:

SHALL TAKE INTO ACCOUNT THE DIFFERENCE IN CONCEPT AND USAGE BETWEEN VARIOUS CLASSES OF PESTICIDES AND DIFFERENCES IN ENVIRONMENTAL RISK AND THE APPROPRIATE DATA FOR EVALUATING SUCH RISK BETWEEN AGRICULTURAL AND NONAGRICULTURAL PESTICIDES.

REPORTS ISSUED BY THIS SUBCOMMITTEE¹ AND THE CONFERENCE COMMITTEE² WERE SIMILARLY SPECIFIC IN EMPHASIZING THAT ANY REGULATION, GUIDELINE OR POLICY MUST CONSIDER THIS IMPORTANT DISTINCTION. EVEN THOUGH NONAGRICULTURAL PESTICIDES ENCOMPASS WELL OVER HALF OF THE CURRENT REGISTRATIONS UNDER THE ACT, WE ARE STILL SEEING DRAFT DOCUMENTS FROM THE AGENCY WHICH FAIL TO MAKE THIS DISTINCTION.

FOR INSTANCE, IN EPA'S MOVEMENT TOWARDS STANDARDIZED LABELING, A SODIUM HYPOCHLORITE PRODUCT, USED AS A DISINFECTANT SANITIZER IN SUCH APPLICATIONS AS LAUNDRY BLEACH AND POTABLE DRINKING WATER, WOULD BE REQUIRED TO BE LABELED WITH THE WORD "DANGER" WITH DIRECTIONS FOR THE USER TO WEAR "GOGGLES OR FACE SHIELD AND RUBBER GLOVES". THE AGENCY STILL DOES NOT TAKE INTO ACCOUNT THAT PRODUCTS FOR HOUSEHOLD USE ARE GENERALLY FORMULATED AT SIGNIFICANTLY LOWER CONCENTRATIONS, AND THEREFORE LOWER TOXICITY.

IN ANOTHER INSTANCE, THE RECENTLY RELEASED DRAFT OF

1. HOUSE OF REPRESENTATIVES REPORT NO. 95-663, 95TH CONGRESS, 1ST SESSION, PAGE 47.
2. HOUSE OF REPRESENTATIVES REPORT NO. 95-1560, 95TH CONGRESS, 2D SESSION, PAGE 42.

SUBPART K OF THE GUIDELINES SPECIFICALLY INCLUDES PESTICIDES FOR HOUSEHOLD AND OTHER INDOOR USES IN REQUIREMENTS FOR WORKER REENTRY DATA.

CSMA SUBMITS THAT IN ALMOST ALL INSTANCES REENTRY DATA SHOULD NOT BE REQUIRED OF GENERAL USE HOUSEHOLD PRODUCTS AND THE GUIDELINES SHOULD SO STATE. IT APPEARS THAT EPA DOES NOT YET APPRECIATE THE NEED TO SEPARATE OUT THE HOME AND GARDEN PORTION OF THE INDUSTRY FROM THE OVERALL INCLUSION IN GENERATION OF REENTRY DATA.

III. FEDERAL PREEMPTION - STATE REGISTRATION ACTIVITIES

THE 1978 AMENDMENTS DELEGATED TO THE STATES ADDITIONAL RESPONSIBILITIES PARTICULARLY IN THE AREA OF ENFORCEMENT, (SEE FIFRA §26 7U.S.C. 136w-1.) IN THE SHORT PERIOD SINCE ENACTMENT OF THESE AMENDMENTS, WE HAVE SEEN CERTAIN MISAPPLICATION BY STATES OF FEDERAL PREROGATIVES.

SOME STATES ARE GOING BEYOND THE AUTHORITY GRANTED FOR SPECIAL LOCAL NEEDS UNDER §24(c)(1) OF FIFRA AND ARE NOW ATTEMPTING TO IMPOSE ADDITIONAL REQUIREMENTS ON FEDERALLY REGISTERED PRODUCTS. AS A RESULT, THERE ARE SUBSTANTIAL PROBLEMS NOW WITH RESPECT TO REGULATION OF OUR INDUSTRY. WE CANNOT STAND BY AND ALLOW FIFTY DIFFERENT REGULATORY SHOES TO DROP WHILE OUR COMPANIES FIGHT INFLATION, FEDERAL GOVERNMENT OVER-REGULATION, AND NOW UNAUTHORIZED STATE LEGISLATION AND/OR REGULATION.

INDUSTRY'S DILEMMA IN STATE REGULATION OF REGISTRATION IS BEST DEMONSTRATED BY THE RECENTLY IMPLEMENTED REGISTRATION REQUIREMENTS IMPOSED BY THE STATE OF CALIFORNIA.

AS A RESULT OF THESE REGULATIONS, SUIT WAS FILED IN THE UNITED STATES DISTRICT COURT, EASTERN DISTRICT OF CALIFORNIA, SPECIFICALLY CHALLENGING THE CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE'S AUTHORITY TO: (1) REGISTER PRODUCTS ALREADY HAVING A FEDERAL REGISTRATION; (2) IMPOSE PACKAGING AND LABELING REQUIREMENTS DIFFERENT FROM THOSE OF THE ENVIRONMENTAL PROTECTION AGENCY; (3) DELEGATE TO COUNTY COMMISSIONERS THE RESPONSIBILITY FOR ISSUANCE OF

PERMITS FOR POSSESSION AND APPLICATION OF RESTRICTED USE AND NON-EXEMPTED AGRICULTURAL PESTICIDES; (4) ESTABLISH TOLERANCES FOR PESTICIDE RESIDUES ON PRODUCE LOWER THAN THOSE ESTABLISHED BY EPA; AND (5) PERMIT THE USE BY FIRMS SUBMITTING COMPETING APPLICATIONS FOR REGISTRATIONS OF TRADE SECRET DATA WITHOUT PAYMENT OF COMPENSATION REQUIRED BY FIFRA.

THE ISSUES RAISED BY THE CALIFORNIA LAWSUIT, IN OUR OPINION, DIRECTLY AFFECT EVERY SINGLE STATE PROGRAM IN THE UNITED STATES.

OF THE FIVE POINTS RECITED ABOVE, THREE ARE OF PARTICULAR IMPORTANCE TO CSMA. FIRST, WE BELIEVE THE STATE OF CALIFORNIA, AND FOR THAT MATTER, EACH OF THE OTHER 49 STATES, DOES NOT HAVE THE AUTHORITY TO REGISTER A PRODUCT AND TO COLLECT FEES FOR THAT REGISTRATION IF THE PRODUCT IS ALREADY FEDERALLY REGISTERED BY EPA EXCEPT FOR ADDITIONAL USES TO MEET SPECIAL LOCAL NEEDS.

SECONDLY, THE STATE OF CALIFORNIA HAS IMPOSED PACKAGING AND LABELING REQUIREMENTS DIFFERENT FROM THOSE SPECIFIED BY THE FEDERAL EPA. WE ARE ABSOLUTELY CERTAIN THAT THE PREEMPTION LANGUAGE IN FIFRA IS CONTROLLING. WITHOUT SUCH A HOLDING, INDUSTRY WILL FACE A BARRAGE OF PROLIFERATION OF PACKAGING REQUIREMENTS WHICH WOULD MAKE IT PHYSICALLY IMPOSSIBLE TO MARKET A PRODUCT NATIONALLY.

FINALLY, A PROVISION CONTAINED IN THE CALIFORNIA REGULATIONS THAT PERMITS THAT STATE TO REQUIRE SUBMISSION OF THE SAME HEALTH AND SAFETY STUDIES AND ENVIRONMENTAL DATA REQUIRED TO BE SUBMITTED TO EPA IN SUPPORT OF A FEDERAL REGISTRATION WITHOUT ADEQUATE CONTROLS AS TO ACCESSIBILITY OF SUCH INFORMATION OR COMPENSATION FOR SUCH DATA, IS UNACCEPTABLE TO OUR INDUSTRY. THE 1978 AMENDMENTS EVOLVING FROM THIS COMMITTEE MADE CERTAIN INFORMATION UNDER §10 OF FIFRA PREVIOUSLY SUBJECT TO PROTECTION AS TRADE SECRET DATA AVAILABLE TO THE PUBLIC, INCLUDING THE STATES, UNDER STRICT RULES OF ACCESS AND ACCOUNTABILITY FOR COMPENSATION

PURPOSES. THE COMPENSATION PROVISION WAS DEVELOPED SO THAT INNOVATIVE FIRMS COULD RECOUP DEVELOPMENTAL COSTS IF THE INFORMATION WAS MADE AVAILABLE TO THE PUBLIC FOR OVERSIGHT PURPOSES. CALIFORNIA'S REGULATIONS DO NOT ADHERE TO THIS STANDARD NOR DO THEY PROVIDE FOR ANY SORT OF COMPENSATION. A COMPETITOR WOULD BE FREE TO USE DATA IN CALIFORNIA TO REGISTER HIS PRODUCT WITHOUT GOING THROUGH THE FEDERAL COMPENSATION AND REGISTRATION PROCESS.

STILL FURTHER ILLUSTRATING OUR CONCERN IS THE RECENT CALIFORNIA ASSEMBLY BILL NO. 3085, INTRODUCED ON MARCH 7, 1980, WHICH WOULD RAISE THE CURRENT ANNUAL REGISTRATION FEE OF \$40.00 FOR EACH PESTICIDE SUBMITTED TO AN INITIAL APPLICATION FEE FOR EACH PESTICIDE REGISTRATION OF \$500.00. IN ADDITION, A FEE OF \$250.00 FOR RENEWAL OF REGISTRATION AND A FEE OF \$250.00 FOR MODIFICATION OF A PRODUCT LABEL WOULD BE CHARGED. CONSIDER THE \$500.00 FEE MULTIPLIED BY 50 STATES FOR A SMALL COMPANY MARKETING 20 PRODUCTS; YOU NOW HAVE \$500,000 IN APPLICATION FEES THAT WILL HAVE TO BE PASSED ON TO THE CONSUMER IF THE COMPANY CAN SURVIVE IN THE FIRST PLACE.

IV. SECTION 6(A)(2) OF FIFRA

SECTION 6(A)(2) OF FIFRA STATES:

IF AT ANY TIME AFTER THE REGISTRATION OF A PESTICIDE THE REGISTRANT HAS ADDITIONAL FACTUAL INFORMATION REGARDING UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT OF THE PESTICIDE, HE SHALL SUBMIT SUCH INFORMATION TO THE ADMINISTRATOR. (EMPHASIS ADDED.)

IN 1977, CSMA BROUGHT SUIT IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA AGAINST EPA SEEKING TO UPHOLD THE STATUTORY LANGUAGE OF §6(A)(2).

EPA, IN THEIR REPORTING REGULATIONS, LEFT OUT THE WORDS "FACTUAL" AND "UNREASONABLE" FROM THE TEXT. THUS, THE REGULATION WOULD HAVE REQUIRED THE REPORTING OF VIRTUALLY ANY INFORMATION COMING TO THE ATTENTION OF THE REGISTRANT WHETHER OR NOT SUCH INFORMATION WAS FACTUAL, OR RELATED TO UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT. INITIAL ATTEMPTS BY CSMA TO HAVE THE REGULATION WITHDRAWN WERE

REJECTED BY EPA. BECAUSE OF THIS, THE ASSOCIATIONS ELECTED TO LITIGATE THE MATTER. AFTER SUIT WAS FILED, EPA THEN DECIDED TO FORMALLY WITHDRAW THE REGULATION AND SUBSEQUENTLY PUBLISHED A MEMORANDUM AS AN INTERPRETIVE OPINION OF THE REGISTRANT'S RESPONSIBILITIES UNDER §6(A)(2) OF FIFRA.

THE LAWSUIT CHALLENGED THE 1978 MEMORANDUM ON GROUNDS THAT (1) IT EXCEEDED STATUTORY AUTHORITY; (2) IT IMPOSED AN UNDUE BURDEN ON THE FIFRA REGISTRANT; AND (3) IT WAS IN FACT A REGULATION AND THEREFORE ITS ENACTMENT VIOLATED THE PUBLIC COMMENT REQUIREMENT CONTAINED IN THE ADMINISTRATIVE PROCEDURE ACT.

THE DISTRICT COURT OPINION OF FEBRUARY 8, 1980 HOLDS THAT THE MEMORANDUM IS NOTHING MORE THAN EPA'S INTERPRETATION OF THE REPORTING REQUIREMENTS, ADDS NO NEW REQUIREMENTS TO THOSE CONTAINED IN THE STATUTE ITSELF AND HAS NO LEGAL EFFECT.

THE COURT FOUND THAT THE DETERMINATION OF WHETHER INFORMATION IS FACTUAL RESTS NOT WITH THE REGISTRANT BUT WITH THE EPA. HENCE, IT APPEARS ON THE BASIS OF THIS DETERMINATION THAT VIRTUALLY ALL INFORMATION MUST BE SUBMITTED TO THE AGENCY. THE STAGE, THEREFORE, IS SET FOR FUTURE CONGRESSIONAL CLARIFICATION.

V. THE "CITE-ALL" REGISTRATION APPROACH

DURING THE COURSE OF TESTIMONY REGARDING THE 1978 AMENDMENTS, THE AGENCY ADVOCATED WHAT IT TERMED A "CITE-ALL" APPROACH TO THE REGISTRATION PROCESS. THE REASONING BEHIND THIS APPROACH WAS THAT BY ALLOWING APPLICANTS TO CITE ALL OF THE DATA IN EPA'S FILES, THE AGENCY COULD THEREBY BE RELIEVED OF THE BURDEN OF EXAMINING SPECIFIC PIECES OF DATA CITED BY APPLICANTS AS TO THE ACCEPTABILITY OF A REGISTRATION. IT WAS BELIEVED THAT THE AGENCY COULD THEREBY USE ITS RESOURCES TO BETTER ADVANTAGE.

THE "CITE-ALL" CONTROVERSY, WHICH BASICALLY ENTAILS CITING ALL OF THE DATA IN THE EPA'S FILES AND MAKING OFFERS TO PAY ALL GENERATORS OF THAT DATA, AFFECTS CSMA MEMBER

FIRMS IN TWO WAYS. FIRST, IN THE CASE OF AN APPLICANT FOR REGISTRATION OF AN END-USE FORMULATION WHO WISHES TO USE HIS OWN TECHNICAL INGREDIENT AND RELY UPON HIS OWN SAFETY AND EFFICACY DATA, THE AGENCY INSISTS NEVERTHELESS THAT SUCH APPLICANTS CITE ALL THE DATA IN THE AGENCY'S FILE AND AGREE TO PAY COMPENSATION TO COMPETITORS.

SECOND, A PRODUCER OF A MANUFACTURING-USE PRODUCT (RAW MATERIAL) IS EXCLUDED FROM RELYING EXCLUSIVELY ON HIS OWN DATA OR SPECIFICALLY CITED DATA EVEN THOUGH FIFRA §3(c)(1)(D) SO PERMITS. SECTION 3(c)(1)(D) STATES:

EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (c)(2)(D) OF THIS SECTION, IF REQUESTED BY THE ADMINISTRATOR, A FULL DESCRIPTION OF THE TESTS MADE AND THE RESULTS THEREOF UPON WHICH THE CLAIMS ARE BASED OR ALTERNATIVELY A CITATION OF DATA THAT APPEARS IN THE PUBLIC LITERATURE OR THAT PREVIOUSLY HAD BEEN SUBMITTED TO THE ADMINISTRATOR AND THAT THE ADMINISTRATOR MAY CONSIDER IN ACCORDANCE WITH THE FOLLOWING PROVISIONS . . .
(EMPHASIS ADDED.)

ON JULY 10, 1979, CSMA SUBMITTED EXTENSIVE COMMENTS TO EPA FULLY DISCUSSING, AMONG OTHER THINGS, THE "CITE-ALL" ISSUES. A COPY OF THIS SUBMISSION IS ATTACHED HERETO FOR THE COMMITTEE'S REVIEW.

VI. DEVELOPMENT OF REGISTRATION GUIDELINES

THE AGENCY PLANS TO PUBLISH ITS PESTICIDE REGISTRATION GUIDELINES IN THE FORM OF THIRTEEN SUBPARTS. AT THIS TIME, ONLY ONE OF THESE, THE REGISTRATION PROCEDURES, HAS BEEN PUBLISHED IN FINAL FORM¹, WITH ONLY THREE OTHERS PUBLISHED AS PROPOSALS² AND THE REST AVAILABLE ONLY AS EARLY DRAFTS³.

1. SUBPART C: REGISTRATION PROCEDURES.
2. SUBPART D: CHEMISTRY REQUIREMENTS; SUBPART E: HAZARD EVALUATION: WILDLIFE AND AQUATIC ORGANISMS; SUBPART F: HAZARD EVALUATION: HUMANS AND DOMESTIC ANIMALS.
3. SUBPART A: PESTICIDE REGISTRATION GUIDELINES: INTRODUCTION; SUBPART B: SUBPART G: PRODUCT PERFORMANCE; SUBPART H: LABEL DEVELOPMENT AND IMPROVEMENT; SUBPART I: EXPERIMENTAL USE PERMITS; SUBPART J: HAZARD EVALUATION: NON-TARGET PLANTS/MICROORGANISMS; SUBPART K: REENTRY DATA REQUIREMENT; SUBPART L: HAZARD EVALUATION: NON-TARGET INSECTS; SUBPART M: DATA REQUIREMENTS FOR BIOLOGICAL PESTICIDES.

YET THE AGENCY CONTINUES TO USE THESE DOCUMENTS IN THE ONGOING REGISTRATION PROCESS AS THE BASIS FOR ISSUING REGISTRATIONS. THIS HAS BEEN THE CAUSE OF CONTINUAL CONFUSION AND FRUSTRATION FOR REGISTRANTS.

ADDITIONALLY, THE AGENCY HAS NEVER MADE PUBLIC ITS EXTENSIVE ADMINISTRATIVE SCHEME FOR THE PROMULGATION OF THESE SUBPARTS, WHICH WE UNDERSTAND CONSISTS OF MORE THAN 60 STEPS, INCLUDING FIVE OPPORTUNITIES FOR PUBLIC COMMENT. CSMA BELIEVES THAT THIS PROCEDURE SHOULD BE SET FORTH IN A FORMAL NOTICE WHICH WOULD GO TO ALL REGISTRANTS AND INTERESTED PARTIES.

WE ALSO BELIEVE THAT IN ORDER TO ENCOURAGE AND ASSIST INTERESTED PARTIES IN PARTICIPATING IN THE DEVELOPMENT OF THESE GUIDELINES, EPA SHOULD PERIODICALLY PUBLISH COMPREHENSIVE UPDATES SHOWING THE STATUS AND FUTURE PLANS FOR THESE SUBPARTS. ALTHOUGH THE RECENTLY PUBLISHED EPA AGENDA OF REGULATIONS IS RECOGNIZED TO BE OF SOME USE IN THIS REGARD, THE LISTING IS FAR FROM COMPREHENSIVE REGARDING THE SPECIFIC ADMINISTRATIVE STATUS OF EACH SUBPART.

VII. GENERIC REGISTRATION (PESTICIDE REGISTRATION STANDARDS)

THE CONGRESSIONAL DIRECTIVE TO THE AGENCY IS CLEAR: TO PROCEED WITH THE REGISTRATION/REREGISTRATION OF PESTICIDES IN A TIMELY AND EQUITABLE MANNER.

DURING THE COURSE OF DEVELOPMENT OF THE 1978 AMENDMENTS TO FIFRA, EPA CONSISTENTLY MAINTAINED THAT INSTALLATION OF A GENERIC OR REGISTRATION STANDARD PROGRAM WOULD ENABLE THE AGENCY TO MORE ADEQUATELY USE ITS RESOURCES, AND AT THE SAME TIME, RESULT IN ELIMINATION OF THE REGISTRATION APPLICATION BACKLOG. TO THE EXTENT THAT THIS SYSTEM WOULD ACCOMPLISH THESE GOALS, WE ARE SUPPORTIVE.

HOWEVER, WE ARE CONCERNED THAT THE AGENCY IS COMMITTING LARGE STAFF AND MONETARY RESOURCES TOWARD THE DEVELOPMENT OF A SYSTEM, THE FRUITION OF WHICH IS DISTANT, AT THE EXPENSE

OF THE MANDATE TO REGISTER/REREGISTER PESTICIDES IN A TIMELY FASHION.

VIII. CONCLUSION

MR. CHAIRMAN, ONCE AGAIN WE THANK THE COMMITTEE FOR THE OPPORTUNITY TO APPEAR BEFORE YOU. AS IN PAST YEARS, WE OFFER OUR SINCERE EFFORTS TO WORK WITH THE COMMITTEE AND INDEED WITH THE AGENCY TOWARD A SMOOTHER IMPLEMENTATION OF THE CONGRESSIONAL MANDATE SET FORTH IN FIFRA. SOME OF THE AREAS WE DISCUSSED THIS MORNING ARE OF GREAT CONCERN TO US AND MAY WARRANT SPECIFIC AMENDATORY LANGUAGE, BOTH TECHNICAL AND PREEMPTIVE.

WE INTEND TO KEEP THE COMMITTEE FULLY INFORMED WITH REGARD TO THESE ISSUES AND WORK TOWARD EFFECTIVE RESOLUTIONS OF THESE PROBLEMS. THANK YOU VERY MUCH.

(The attachment to the statement is held in the subcommittee file.)

MR. DE LA GARZA. Thank you very much. Mr. Fithian?

MR. FITHIAN. Thank you, Mr. Chairman. Thank you, Mr. Engel, for your testimony.

I would like to explore the case where a State registration requirement exceeds, or is higher than the Federal. You cite in your testimony the State of California. The conflict is more than a philosophical one, I am sure, but it is, at least, a philosophical one. That is a question of States' rights issue versus the Federal preemption issue. You have raised, rightly, the monetary side of that, but there is a difficulty which I am sure you are aware of. You allude to it in your testimony. The difficulty is whether or not the Federal Government can, in fact, preempt in cases such as these. I would just reflect upon your testimony as you gave it. It called to mind the Clean Air Act provisions in which the State of California does have higher controls than the Federal Government.

Mr. Chairman, I do not know whether it has ever been tested in court, but I do know that in order to have an automobile in California it has to meet certain standards. I would be interested in a brief commentary by you as to how the Federal Government can proceed to justify in this case the right of the State to set standards higher than the Federal Government does nationwide.

MR. ENGEL. First, I think it is difficult to compare emissions with a factory. There are specific points in the lawsuit that has been filed by CSMA that are of concern to us. One is labeling of a product. If indeed California requires a different label than the Federal requirements call for, our companies then have to package two different products.

MR. FITHIAN. I understand that, but I guess my question is this. How do we justify, philosophically, the Federal Government preempting the right of California to perhaps give additional warning to its citizens if the State of California deems that in its particular case that kind of warning is necessary?

MR. ACKERLY. Mr. Fithian, it is a philosophical discussion. In California the auto emission standards were in place before Federal legislation was passed. Congress, in its wisdom, chose to respect California for being there first. These products move in interstate commerce. The Clean Air Act emission, particularly with stationary sources, are not in interstate commerce. It is a matter of philosophical judgment—

MR. FITHIAN. Detroit sells a car to California. It sells the same car to Ohio and Washington, D.C. Obviously, that is interstate commerce.

MR. ACKERLY. The regulations in California were in place before the DOT regulations. The difference in cost is something like \$100, and it is easy, apparently, for Detroit to put out an automobile for California with just a little more of an emission control—for an extra \$100. They choose not to do that as a matter of economics, and maybe it is not necessary for marketing it throughout the rest of the country.

California has no prerogative on States' rights. There are 50 States that require registration of pesticides today. Labeling and providing test data for 50 States would be ruinous and wholly unnecessary.

We cannot indulge the presumption that EPA is not effective in what they do. California has the same opportunity to go to EPA and press for regulations as any other States. EPA sits as an arbitrator, if you will, under the statute, to listen to California's problems or those of

Texas or Michigan and the industry and come out with reasonable regulations nationwide.

Suppose different States had different tolerances on agriculture commodities. How could you market anything? How could a farmer in Indiana market anything in California or vice versa?

The commerce clause, I think, recognizes that States' rights are important, but that regulation of interstate commerce cannot permit the disruptive effect of a whole series of regulations whether it be mud flaps on trucks or registration of pesticides.

Mr. FITHIAN. I appreciate your remarks and thank you for that. It is obviously a very difficult question and one which we are caught in, as I think you objectively realize. We rest on the horns of a dilemma.

By and large the American people believe the Federal Government is too powerful, and that we ought to leave more of these things to the States and individuals.

But in this case the thrust of your testimony is to make the Federal Government even more powerful and therefore preemptive of these States' rights—in this case California, to require additional registration requirements or additional data, whatever California decides to do.

Thank you, Mr. Chairman.

Mr. DE LA GARZA. Mr. Wampler?

Mr. WAMPLER. I have no questions.

Mr. DE LA GARZA. We appreciate your testimony.

I might mention that if we were to imply in any way that we were going to preempt FIFRA entirely, we would have 50 Governors, the Governors of Puerto Rico, the Virgin Islands, and the territory of Guam here at the next hearing. So it is something that we are going to look at very, very carefully. We have to see if there is some way we can come up with some solution to what both of you gentlemen and the previous witness have mentioned with relation to the inconsistency in California. It seems they do everything differently there.

Mr. ENGEL. Mr. Chairman, that inconsistency is starting to slop over into a few other States as well now. As soon as one State gets something, then another sort of jumps on the bandwagon.

Going back to Mr. Fithian's comment, we are not advocating more big government. We are essentially advocating uniformity here.

Mr. WAMPLER. We could repeal FIFRA and start over, maybe.

Mr. ENGEL. Well, I think it is pretty good opinion.

Mr. WAMPLER. I am not sure I want to go through that again.

Mr. DE LA GARZA. We will be older and grayer.

Thank you very much. We appreciate your testimony.

Mr. ENGEL. Thank you.

Mr. DE LA GARZA. The next witness is Mr. Robert Russell, Orkin Pest Control.

We welcome you, and we are happy to hear from you at this time.

STATEMENT OF ROBERT M. RUSSELL, VICE PRESIDENT, GOVERNMENT RELATIONS, ORKIN EXTERMINATING CO., DIVISION OF ROLLINS, INC.

Mr. RUSSELL. Thank you, Mr. Chairman.

I am appreciative of the opportunity to testify before this committee on this consequential legislation. My name is Robert Russell,

and I am vice president, government relations of the Orkin Exterminating Co. We are a division of Rollins, Inc., and a member of the NPCA.

As you probably know, Orkin is the largest structural pest control and termite control company in the world. We operate in 41 States, the District of Columbia, and Mexico. Our interest in FIFRA is on behalf of our customers, our people, and others in our industry who must abide by this law and EPA regulations.

We have testified for and supported pesticide legislation beginning with amended FIFRA in 1971. We still support that sound legislation and regulations are beneficial. There are, however, three areas relating to FIFRA which are presently a concern to us.

First, the Federal Pesticide Act of 1978 introduced State primacy enforcement responsibility with the passage of sections 26 and 27. We supported this concept for it can eliminate double cost to government and double jeopardy to industry. Though the primacy amendments passed in September 1978, there are still no regulations to properly guide the States and industry who are affected. Our industry feels very strongly that these regulations must reflect not only the law itself, but the clearly declared intent of the legislative history of these amendments. We seek no relief from enforcement, but we do believe we are entitled to State primacy enforcement as provided by law and as defined by legislative history.

Law and regulation provide the safe and sensible use of pesticides for the ultimate benefit of the people. The law on State primacy enforcement established the Agency as the reviewing authority, the States as the enforcement arm, and industry as the complying user. So that the public can best be served, all three components of this arrangement—review, enforce, and use—need to work together to build the regulations. For there is unique and contributory knowledge in each of the three components.

Since 1978, we have maintained contact with the Agency offering to serve as a contributor in building proper regulation. We can best contribute if we have the opportunity to input during development and certainly prior to publication. Once regulations are published, there is little, if any, change ever enacted. So to help, we need to contribute to the building of the regulations.

Next, a cooperative enforcement grant is one of the devices established by the State primacy amendments, section 26(b), to assign enforcement authority to the States. Also, the review and acceptance of a section 4 State plan. The Agency has acknowledged these routes for assignment as was noted on page 11 of Mr. Jellinek's presentation to this committee, April 24, 1979. However, most enforcement grants seem to have been written prior to the September 1978 passage of the State primacy amendment. For an Agency letter of November 1979 states:

... inspectors are authorized to use either State or Federal credentials so long as they make clear at the time of their inspection under which authority they are acting. Any evidence of violations can subsequently be used in either a State or Federal prosecution or both.

In our understanding, this is not the intent of the law. For House Report No. 95-1560, page 41 states:

The Administrator may not use the cooperative agreements entered into under section 23 of FIFRA to obtain dual enforcement responsibility with the States.

Finally, there is another area of concern to us. Section 27(a) includes this:

(a) Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this Act. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or information to the extent authorized under this Act.

The key word here may well be "appropriate." We would not want the Agency to so interpret "appropriate" as to negate the suitable conduct of a State primacy enforcement program. The law and legislative history grants primacy to the State. As authority is granted to the States, they must have reasonable latitude to conduct the enforcement program. The Agency role should remain as that of reviewing authority and EPA should not attempt to make a dual enforcement role for itself.

In summary, we believe we can contribute to State primacy enforcement regulations and want to do so in the development stage.

Next, the cooperative enforcement grants need to reflect both the law and the legislative history. We do not believe they should be used to establish a dual enforcement program.

Further, the interpretation of the word "appropriate" in the primacy regulations should also not limit the rights of the States to conduct their legally granted enforcement programs.

Safe and sensible pesticide use contributes to the best and most abundant food supply of any nation in the world. This committee has contributed significantly to a balanced pesticide use position. For that, we are appreciative. We sincerely hope the influence of the committee will continue to assist the Agency in correctly executing FIFRA.

I thank you for permitting me to speak to you for my company, Orkin, for the structural pest control industry, and for the ultimate benefit to the people we serve.

Mr. DE LA GARZA. Are there any questions of Mr. Russell? Mr. Fithian?

Mr. FITHIAN. I want to thank Mr. Russell for their very detailed communication to me back in February outlining some of the problems. I have not had a chance to thank you for that letter and for the details with which you supplied me. I appreciate that.

Mr. RUSSELL. Thank you, sir.

Mr. DE LA GARZA. Mr. Wampler?

Mr. WAMPLER. I have no questions.

Mr. DE LA GARZA. Thank you very much, Mr. Russell.

Mr. RUSSELL. Thank you.

Mr. DE LA GARZA. Our next witness is Mr. Charles Hromada. Terminix International, Inc. of Memphis, Tenn.

Mr. Hromada, we welcome you to the subcommittee.

**STATEMENT OF CHARLES HROMADA, SENIOR VICE PRESIDENT,
TERMINIX INTERNATIONAL, INC., MEMPHIS, TENN.**

Mr. HROMADA. Thank you, Mr. Chairman. My name is Charles Hromada, and I am senior vice president of Terminix International, Inc. from Memphis, Tenn.

We support H.R. 7018, and we are not asking for any language changes to FIFRA at this time. I do, however, want to testify today concerning what I regard as unwarranted involvement and interference by the Environmental Protection Agency in State programs for the enforcement of pesticide use violations.

Although this subcommittee and the Congress provided in the Federal Pesticide Act of 1978 that States should be given primary enforcement responsibility under FIFRA, the EPA has continuously, I think, ignored the letter and the spirit of those 1978 amendments to the law. I would like to describe a couple of cases thereto.

As you know, sections 26 and 27 of the Federal Insecticide, Fungicide, and Rodenticide Act as amended in 1978, permit individual States to assume primary responsibility for the enforcement of pesticide use violations. These sections were developed for the most part through the effective work of this subcommittee and the full Committee on Agriculture. It is clear from the language and the legislative history of these amendments that where States have primary enforcement responsibility, EPA can undertake Federal enforcement action only under specifically defined circumstances.

Under section 27(a) of FIFRA, if EPA becomes aware of a significant—and I think that is a very important word—use violation, it can refer the matter to the appropriate State officials for their investigation. If the State does not commence appropriate enforcement action within 30 days, the Administrator may undertake Federal enforcement action.

In the first year since the passage of the 1978 amendments, the EPA often acted as if this section just did not exist. More specifically, EPA officials would review State files and pull our cases where they felt that appropriate enforcement action had not been taken by the State. Most of these cases, by the way, had already been investigated and closed by the State authorities. EPA would then send a notice of Federal violation directly to the pest control operator. The State officials were never informed of EPA's intervention, let alone given an opportunity to review their own enforcement action as required under section 27(a). Only following extensive industry opposition and the intervention of interested Congressmen on this committee did the Agency finally issue a directive to its regional offices to cease such practice.

However, in all the cases that I am aware of, EPA, after withdrawing their first citation, gave immediate notice that the matter would be referred to the State, which was given 30 days to commence appropriate enforcement action.

I wish to stress that in the cases involving Terminix, the North Carolina State officials had already reviewed the alleged violations and completed their enforcement action. In each case, the violation was determined to be a minor discrepancy, and in each case the discrepancy had been corrected. The violation was not judged significant enough by the State to require a major enforcement action. And in each of these cases, the decisions were reviewed and approved by the attorney general's office of North Carolina.

Section 27(a) provides that the Administrator may refer only significant pesticide violations to the States for review and commencement of appropriate enforcement actions. However, the North Carolina cases can by no stretch of the imagination be considered significant

violations of the Federal law. EPA's attempt to get the State to reopen these cases is tantamount to dual Federal-State enforcement. Yet, the primary purpose of the 1978 amendments to FIFRA was to eliminate dual enforcement.

Before continuing, I would like to point out that I am not asking this committee to intervene specifically in these cases. I am only trying to inform them as to some of the activities in the enforcement area and EPA's practice under section 27 of FIFRA.

The cases which I describe in detail here I think you will agree that they are minor discrepancies, if any at all.

In March 1979, employees of Terminix prepared a residential structure in North Carolina for fumigation for certain pests. Pursuant to North Carolina law, State official inspectors had been given prior notice and were present at the job site. Prior to the introduction of the pesticide into the residence, the question arose as to whether or not the pesticide to be used was labeled for use in such structures. Although the label on the containers themselves did not mention such use, it did make reference to additional proper use in a bulletin prepared by the manufacturer of the pesticide in question. Since the bulletin was not at the site, the fumigator and the State inspector called the manufacturer, who confirmed that the pesticide was registered for use in the present situation. The fumigator asked that copies of the additional labeling be sent immediately to his office. The fumigation job was then completed with State inspectors present.

Since the State law did require that the supplementary labeling be on the job site, the fumigator was given 30 days to correct the discrepancy. The discrepancy was corrected and the matter was then closed. An identical fumigation job was completed on March 28, under the same circumstances with a State inspector present.

In the view of the State, the violation was technical or a minor discrepancy, in that all of the labeling was not on the job site. It was clear that the pesticide was registered for the use made of it and that there was no danger to the environment from its use. Notwithstanding the minor nature of the discrepancy, EPA has now asked the State to reopen its case and commence an appropriate enforcement action. The State is under some pressure to comply, since it does not want to jeopardize its Federal cooperative enforcement grant money. However, if the State refuses to change its determination, EPA will then bring its own enforcement action.

This will be done in cases which are clearly not significant violations of FIFRA, as is required under section 27(a). The State officials, I would point out, are also highly critical of EPA's actions in these cases. It is their view that EPA intervention in such cases will not enable them to carry out their own State programs. I want to say that I have to agree with their conclusion.

I am hopeful that these activities can be resolved and settled without any further EPA enforcement activity after the State responds to the 30-day referral notice.

Terminix, and I am sure this is true for other members of the pest control industry, does not intend to avoid pesticide use enforcement. It undertakes a major effort to insure compliance with both the Federal

and State Laws under which it operates. What Terminix does not want is dual enforcement, or Federal interference with State enforcement programs under which we work daily and operate under.

I would hope that the subcommittee would do what it can to insure that the Agency recognizes and complies with the 1978 amendments to FIFRA and that the States are able to carry out their primary enforcement responsibilities as envisioned under the amendments of 1978.

This concludes my testimony. I would be happy to answer any questions which you or any of the other committee members may have.

Thank you, Mr. Chairman.

Mr. DE LA GARZA. Thank you very much, Mr. Hromada. Are there any questions?

Mr. FITHIAN. I have no questions.

Mr. WAMPLER. I have no questions, Mr. Chairman.

Mr. DE LA GARZA. Thank you very much. We appreciate your testimony.

Our next witness is Mr. Harold Collins, Jr., National Agricultural Aviation Association, Washington, D.C.

Before you begin, is Dr. Scott Whitney here, or Bruce Hawley and Jack Grimes? Only Mr. Hawley? It seems we are running a little bit ahead of schedule. If you would want to testify this morning, Mr. Hawley, that will make a shorter period this afternoon. Thank you very much.

You may proceed, Mr. Collins.

STATEMENT OF HAROLD M. COLLINS, JR., DIRECTOR, GOVERNMENT AFFAIRS, NATIONAL AGRICULTURAL AVIATION ASSOCIATION, WASHINGTON, D.C.

Mr. COLLINS. Thank you, Mr. Chairman.

Mr. DE LA GARZA. Before you begin, Mr. Collins, I want to say that without objection, your entire statement will appear in the record, and you may summarize or do whatever you wish.

Mr. COLLINS. Thank you. We would like to begin this morning by saying that we have experienced a degree of cooperation with the Agency during the past year in some areas, which we believe is very productive.

However, there are some areas that we would like to bring to your attention and the Agency's attention again.

This has to do with our business which is aerial application. We are representative of about 33 percent of the aerial applicators in the United States. There are approximately 3,000 operating companies representing about 8,600 aircraft, 600 of which are rotorcraft or helicopters.

We treat 180 million acres annually at least once. Cotton, for example, may be treated as many as 10 or 15 times, depending on the nature of the season. So, the ultimate treatment may extend upward of 360 million acres total.

As such, we have a very high public exposure, and we believe that over the years with the improvement in both pesticides and application equipment, the business has improved and become a very professional kind of business.

During the past year, however, and into 1978, there were some changes made that have caused our membership some substantial concern. This would include primarily three major categories, one of which is the low volume/ultra low volume method of application.

This was addressed in the amended FIFRA of 1978 and resulted in the ability of the applicator to use the label to make his application of pesticide at dilutions lesser than those required by label up until the Agency issued its report to the Congress as mandated by the law on March 31, 1979. From that time until July 9, the application world was able to proceed at will, and, of course, the season was well underway. At this point the Agency issued an advisory opinion suggesting that we could no longer dilute pesticides lesser than that indicated by label.

This announcement appeared in the Federal Register, and I wonder, sir, how many pesticide applicators in the country actually read the Federal Register every day. I wonder, in fact, just how effectively the application techniques were monitored in 1979?

It was a case of concern to both State government and applicators alike, such that they asked the Agency to consider a second opinion because historically the Agency had issued pesticide enforcement policy statements which allowed for variation in label. They had issued special prosecutorial discretion statements which allow for variation in label for low-volume applications. Because we had a successful history of use, we were unaware also that in any enforcement actions that would indicate that these were particularly hazardous in producing unreasonable adverse effects on health or the environment.

In any event, we entered 1980 at the pleading of State government with no further definitive instruction. We would certainly hope that sometime during this year more consideration will be given to allow for application techniques that have been used successfully in the past and to our knowledge have no unreasonable adverse effects at the present time.

In addition to that, in October 1979, an advisory opinion was issued specifically for the State of Arizona and specifically on cotton defoliant applications. Again, because of alleged health concerns of citizens living adjacent to agricultural areas this was done.

We are very concerned here because the Agency made specific recommendations with regard to application equipment, and we were unaware that the Agency had jurisdiction over application equipment. From my own personal field of experience, I know that application equipment varies all over the country, and between two users of equipment it will be different simply by their alteration of the equipment to meet their specific needs.

So, when we get into label amendments, which this seemed to be, specifying specific nozzle sizes, pressure, aircraft speed, buffer zones, and so on, these were label amendments that seemed to be made without response to section 3 of the FIFRA which is the proper procedure to follow when amendment labels. We wonder further whether the registrants were even aware of this.

Finally, this year in January, the Friends of the Earth petition appeared in the Federal Register with regard to public concern over the health impact of pesticides. We share this concern—so much so that

we have initiated an NAAA survey which is a study of the health of Ag pilots who have been spraying, many of them for 30 or more years. This includes their spouses, their children and the siblings—the brothers and sisters of the Ag pilot—and their families in an attempt to once and for all identify what voluntary, repetitive, high-level exposure—far more than the general public experiences—what is the impact of this on human health. We believe this is representative of the real world in that everyone is exposed, perhaps, to pesticides from simple things like backyard spraying or lawn spraying in the urban community right out of the agricultural community where the farm family lives in the center of a farm that is being treated repetitively.

Hopefully, this survey will shed some light on the health concerns we all share, and this survey should be completed by the end of this year.

We know that a number of the members participating in this survey have been extensive users of 2,4,5-T, which is the subject of much public debate. We know, too, that the people participating in this survey—the spouses particularly—are women who were working with their husbands as mixers, loaders, and baggers under the aircraft and around the aircraft during their childbearing years. So, we believe that we will make some positive contribution.

We are also participating this year with USDA in a similar exposure study on one specific chemical which is not necessarily normal among the application community. They generally work with many chemicals. In any event, we are hopeful that this will make a contribution.

Finally, we would like very much to see consideration given on the part of the experts within four major Government departments. These include EPA, USDA, FAA and NASA. This is for an inter-agency agreement whereby they could use the facilities and expertise within each department to find ways to improve within the existing technology pesticide application techniques such that we will further reduce insult to health and/or the environment.

With that I conclude my remarks, and I would welcome any questions. Thank you.

Mr. FITHIAN [acting chairman]. Thank you, Mr. Collins, for your refreshing testimony. We hope that you will share the results of your well-designed and, I think, very thoughtful assessment of impact on health.

Mr. Wampler, do you have any questions?

Mr. WAMPLER. Thank you, Mr. Chairman. I just want to thank Mr. Collins for being here this morning. I am looking forward with a great deal of anticipation to the results of your survey that is being made on exposure experience of the members of your association and their families.

Let me ask you one other question, Mr. Collins. This is not necessarily on the basis of your testimony, but your association, I am sure, has been heavily involved in the application of 2,4,5-T, particularly in silviculture—in spraying stands of timber.

It is my understanding that in banning the use of 2,4,5-T, as a practical matter you would have to perhaps apply three or four different herbicides to get the same basic coverage or protection that 2,4,5-T affords. Is that correct?

Mr. COLLINS. In my experience, sir, in the release of conifer vegetation in the forestry world, the only chemical I know that works effectively from aircraft and economically is 2,4,5-T. There are alternative materials available to other noncropland uses of the phenoxy herbicides, some of which are more expensive, and some of which are not as wide spectrum in the degree of control on given woody species, and would result, perhaps, in repetitive applications of more pesticide than you might normally experience with 2,4,5-T.

Mr. WAMPLER. Thank you.

Mr. FITHIAN. We thank you, Mr. Collins, for being here this morning and for your testimony.

Mr. COLLINS. Thank you.

STATEMENT BY

HAROLD M. COLLINS, JR.

DIRECTOR OF GOVERNMENT AFFAIRS

NATIONAL AGRICULTURAL AVIATION ASSOCIATION

Mr. Chairman, the National Agricultural Aviation Association (NAAA) thanks you and members of the Department Investigations, Oversight, and Research Sub-Committee for providing us with an opportunity to comment before you today. My name is Harold M. Collins and I am NAAA's Director of Government Affairs. NAAA is a trade association whose membership includes aerial applicators and allied industry throughout the nation. Our pilot members apply seed, fertilizer, and pesticides to the properties of food and fiber producers of this country. Based on United States Department of Agriculture data, aerial applicators apply nearly sixty percent of the pesticides used domestically. To accomplish this task, applicators fly approximately 8600 aircraft for a total of 2,645,000 hours annually. In this regard, we have substantial interest in meeting the full requirements of the Federal Insecticide, Fungicide, and Rodenticide Act, as Amended (FIFRA). As a participant in the initial development of this law as well as subsequent modifications and regulations pursuant thereto we continue to endorse the need for such a law and effective administration thereof on the part of the Environmental Protection Agency (EPA).

On this basis we encourage the committee to extend again the FIFRA, as amended, for one (1) year.

Now, as we were a year ago, NAAA is highly concerned over the Agency's handling of the Low Volume (LV)/Ultra Low Volume (ULV) methods of pesticide application. Public Law 95-396, dated September 30, 1978 amended the Federal Insecticide, Fungicide, and Rodenticide Act, as amended

(FIFRA). With regard to LV/ULV methods of pesticide application it reads as follows:

"(ee) TO USE ANY REGISTERED PESTICIDE IN A MANNER INCONSISTENT WITH ITS LABELING. The term 'to use any registered pesticide in a manner inconsistent with its labeling' means to use any registered pesticide in a manner not permitted by the labeling: Provided, That the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27 (b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution."

On July 10, 1979 the Environmental Protection Agency issued a notice in the Federal Register providing an advisory opinion regarding ULV pesticide applications. The following excerpt from that advisory opinion clearly identifies the Agency's current position on ULV spraying: "Accordingly, until further notice, all persons using pesticides must follow instructions concerning amounts of dilution as specified in: (1) Federally registered pesticide product labeling; (2) State labeling issued under FIFRA Section 24 (c); or (3) an emergency exemption issued under FIFRA Section 18. The use of a pesticide with any amount of dilution less (Increased concentration) than that specified by any one of the three examples above is a violation of Section 12 (a) (2) (G)."

We question too the ability of the Agency to provide label instructions for products without full utilization of Section 3 requirements regarding product registration. In the case of cotton defoliants, we are unaware that product registrants would agree to the Agency label additions.

The Environmental Protection Agency has expressed substantial concern regarding involuntary exposure to pesticides. Involuntary exposure occurs via three routes.

1. Residue in the food we eat.
2. Exposure to spray drift.
3. Exposure as a consequence of entering treated areas, such as farm fields and places of public recreation.

Since aerial applicators are voluntarily and repetitively exposed to pesticides at levels far greater than the general public, a health survey was initiated in October of 1979. Results of this survey will be available to government and all interested parties by December of 1980. We are most hopeful that this effort will provide substantial assistance to government and pesticide users alike. The results of this survey could have substantial impact on future regulatory actions with regard to pesticide application by commercial, rural, and urban users. Since such a wide range of pesticide products are common to all of the groups indicated, regulatory actions might well be universal to all user groups.

During the remainder of 1980 NAAA is hopeful that the Agency will conclude and make public many of the health studies which have been contracted for by them. These, in combination with outside health studies, should provide adequate information to develop pesticide use regulations consistent with the needs of the people and the agricultural community.

One such mechanism to accomplish this goal would be an inter-agency agreement to allow the expertise of EPA, USDA, FAA, and NASA to combine in a study of pesticide application that would provide for optimum protection of health and environment without detracting from this nation's agricultural productivity. Such an activity would be in the best interest of integrated pest management, public health and safety, and agricultural productivity. NAAA would welcome an opportunity to participate in such an endeavor.

In conclusion, this association hopes that a one-year extension of the FIFRA will provide the Agency with ample time to demonstrate a better understanding of the needs of individual states, pesticide applicators, and the general public. We thank you for this opportunity to appear before you and will be pleased to address any questions you may have.

Mr. FITHIAN. We will now proceed with a witness who was scheduled for this afternoon. We will hear from Mr. Bruce Hawley of the American Farm Bureau Federation.

Mr. Hawley, you may proceed as you see fit at this time.

It is always good to have you back with us in this committee.

STATEMENT OF BRUCE HAWLEY, ASSISTANT DIRECTOR, NATIONAL AFFAIRS DIVISION, AMERICAN FARM BUREAU FEDERATION

Mr. HAWLEY. Thank you, Mr. Chairman.

The American Farm Bureau Federation is a general farm organization in 49 States and Puerto Rico. Farm Bureau membership exceeds 3 million member families. We appreciate this opportunity to share with this committee our concerns about EPA's pesticide program.

Farmers and ranchers are in serious economic difficulty. In addition to the same problems with inflation as the remainder of the U.S. economy, the grain embargo had had a significant impact on prices and the short-term marketability of grain. The ability to convert stored commodities into cash for spring production expenses is limited. Short-term financing is very expensive. Input costs, particularly energy-related input costs, have increased dramatically. We anticipate at least a 25-percent decline in net farm income this year. The committee is, of course, aware of the seriousness and significance of these problems.

Supplementing the dramatic problems as outlined above, farmers continue to face unnecessary difficulty and expense because of EPA's mismanagement of the pesticide program.

Sheep raisers continue to lose unacceptable levels of their lamb crop because of EPA's refusal to allow the use of important predator control chemicals.

Fire ants have infested nearly 230 million acres across the Southeast. The area of infestation spreads yearly and EPA continues to make unfulfilled promises of a solution.

USDA projects grasshopper infestation in the Midwest at economic levels on 32.2 million acres of land. Last year's efforts to maintain a grasshopper control program were thwarted because of environmental concerns.

Cotton farmers are told that they may not use conventional pest control programs within a quarter of a mile of the fence row in some areas where new neighbors have complained. This year, like last year and the year before, farmers, farm organizations, land-grant colleges and others must spend hundreds of thousands of dollars to collect scientific information to rebut allegations advanced against individual pesticides by EPA.

When FIFRA was passed in 1972, it charged the Environmental Protection Agency with the clear responsibility of registering pesticides, classifying pesticides for restricted or general use, and of certifying applicators to use restricted-use pesticides. In 1978, significant revisions of the law were passed to provide expedited mechanisms for the achievement of the original purposes of FIFRA. Today EPA has reviewed and reregistered less than one-half of all registered pesticide

uses and only one-tenth of all registered pesticides. That is 127 of the some 1,200 active ingredients.

Beyond our concerns with what EPA has failed to do, we are concerned with the operation of some of the ongoing programs. The RPAR program operation continues to cause farmers serious problems. The case history of a specific RPAR'd chemical will illustrate the point.

On May 25, 1977, EPA initiated an RPAR against all major uses of Toxaphene. Toxaphene was, at that time, one of the more important insecticides used in production agriculture. In the process of initiating the RPAR, EPA alleged serious environmental and human health hazards. The Agency provided 4 months for users and industry to respond to these allegations. That was almost 3 years ago. The use of Toxaphene has dropped dramatically, partly in response to the concern about safety raised by EPA.

Farmers and ranchers have traveled to hearings to testify about their experiences with this pesticide and industry has spent untold thousands of dollars developing data demanded by EPA. In the Agency's 3 years of review, they have apparently not yet come up with enough information to justify a regulatory action against Toxaphene. We understand that EPA may come out with a position document on Toxaphene some time this summer. We understand further that the position document would assess Toxaphene's economic merit based on the 1-year experience of the 1979 crop year, an extraordinarily low pest outbreak year. USDA provided data derived from more normal pest outbreak years, which was rejected by EPA.

We do not appear before the committee today to testify in support of Toxaphene. We merely use Toxaphene as a point to illustrate a Government system that is not functioning properly. There are several Toxaphene-like stories.

There are many RPAR pesticides like Toxaphene. They have been outstanding for a number of years—2 or 3 years—without ever coming to a resolution of the specific concerns.

Farmers and ranchers are the group with the highest exposure of any user group in the country of pesticides. When EPA says there is a problem, we must, as responsible, concerned citizens—concern for our own health, for our families, health, and for the environment, take cognizance of those concerns when raised by EPA. We think we are entitled to a responsible resolution of the questions raised by EPA in a time manner so we continue to know what tools are available for purposes of pest control and crop production.

A second area of concern is the emergence of regulation-like restrictions unilaterally imposed against chemical use outside of the regulatory process. Within the past few months, EPA has recommended buffers, ranging from 250 feet to 1 mile, between areas of pesticide application and roads, residences and, in some instances, crops. In each instance EPA has stated that the buffers are not a requirement, but failure to follow could lead to enforcement action.

The 1978 amendments to FIFRA were intended to increase the role of science in EPA's decisionmaking process and to insure USDA, congressional, and public input prior to regulation implementation. We view these recent developments as efforts to circumvent the intent and requirements of law.

As a part of the reauthorization process, we urge this committee to direct EPA to get on with the basic business of FIFRA, the registration and classification of pesticides and certification of applicators, as a first priority. This year, more than most, farmers and ranchers of the United States cannot afford to comply with scientifically unsound regulatory requirements or the seemingly unending demand for additional data that has marked EPA's implementation of FIFRA.

We thank you for this opportunity to comment.

Mr. FITHIAN. Thank you, Mr. Hawley. Mr. Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman.

Thank you for your statement, Mr. Hawley. I think you have given this committee a good deal to think about, particularly with the timely relationship of needless regulations to productivity and what it is going to contribute to some of the root causes of inflation.

Perhaps you heard the earlier question of mine about legislation I have introduced which will establish a new concept in making scientific determinations for regulatory purposes in the establishment of an independent national science council. Have you had an opportunity to review this legislation? Do you have any views that you might share with the committee on it?

Mr. HAWLEY. Yes; we have had a chance to review it, Mr. Wampler. The initial review conducted by my staff and myself for the Farm Bureau was most favorable to the bill. I felt that it was a responsible effort to bring science as a key player into the decisionmaking process at the Federal level.

Subsequently, we prepared a report and submitted it to the board of directors of the American Farm Bureau with the recommendation that they consider this bill as one of our high-priority legislative items. They reviewed the legislation, and its content, and unanimously concurred that this clearly is something that the Farm Bureau must be in support of.

Mr. WAMPLER. I appreciate your statement very much. Of course, the concluding sentence in your statement this morning includes the language "scientifically unsound regulatory requirements or the seemingly unending demand for additional data" and so forth.

I don't think any of us want to do anything that would cause irreparable damage to the environment or human health. But I am aware of many documented cases where I feel that regulators have acted on the basis of unsound scientific data. I think we can call to mind immediately the cases of nitrites used as preservatives in food and others that are currently before the Congress.

So, I do appreciate your statement very much.

Mr. HAWLEY. Thank you.

Mr. FITHIAN. I want to second Mr. Wampler's comments this morning. I appreciate your testifying. I appreciate also your accommodating the committee by testifying earlier than you had intended to. I don't know if that means you get the afternoon off or not.

Mr. HAWLEY. Probably not.

Mr. FITHIAN. Thank you for your testimony.

Mr. HAWLEY. Thank you, Mr. Chairman.

Mr. FITHIAN. With that, the subcommittee will stand adjourned until 2 p.m., this afternoon.

[Whereupon at 11:25 a.m. the subcommittee was recessed to reconvene later the same day.]

AFTERNOON SESSION

Mr. DE LA GARZA. The subcommittee will be in order. We have one witness for the afternoon session.

Mr. Wampler has been detained, but is on his way. He sent word for us to begin. The hearing will have as its last witness today, Mr. Jack Grimes, National Pest Control Association.

Mr. GRIMES. With the change in schedule, I understand that Mr. Robert Russell and Mr. Charles Hromada have presented their statements already.

Mr. DE LA GARZA. Yes; they have.

Mr. GRIMES. I understand that they focused almost completely on the first item in my agenda. So, I will pretty much tend to pass that over. It is not to give it any less emphasis, but it is to emphasize that we think it is a very important issue—the question of State primacy.

Mr. DE LA GARZA. That will be fine, Mr. Grimes. You may proceed as you see fit.

STATEMENT OF A. JACK GRIMES, DIRECTOR, GOVERNMENT AFFAIRS, NATIONAL PEST CONTROL ASSOCIATION, VIENNA, VA.

Mr. GRIMES. Mr. Chairman and members of the committee, I am director of Government Affairs for the National Pest Control Association. I want the record to indicate that NPCA is the national membership association of the owner/operators of structural pest control companies of the United States.

Structural pest control is not necessarily a good descriptive title, but for the record I do want to indicate that this industry is concerned with identifying and controlling pests that invade our homes, offices, factories and warehouses. This industry is the Nation's defense against economic and aesthetic losses from all species of organisms that infest building structures or their contents. Our members also fight the battle to keep our food supplies free of contamination from pests once food leaves the field.

Structural pest control operators work to reduce the losses of the Nation's food supplies from pest infestations during storage, transportation, processing and distribution right up to the time it is consumed.

We protect the public's health from pests that serve as carriers of filth and disease as well as from those organisms that are just common nuisances such as ants, spiders, and scorpions.

The next paragraph of my statement is one that I think deserves emphasis.

The structural pest control industry has used integrated pest management for many years. It has not and does not now depend exclusively on pesticides for effectiveness in its work, although pesticides are an important resource for eliminating and controlling certain infestations. The members of this industry depend primarily upon their knowledge of pest biology and behavior and their experience with a diversity of control methods appropriate for the site rather

than dependence upon pesticides likely to be hazardous to them or their customers.

I think it is important to realize that the structural pest control industry uses—probably 95 percent of the pesticides they use are the same ones that are available to the general public.

Early in the 1970's NPCA supported the legislation which gave the EPA authority to regulate the use of pesticides. The association actively supported EPA's approved programs of certification of persons who apply or supervise technicians in applying, pesticides that are classified by EPA as for "restricted use."

It is and has been the policy of NPCA, and thus its membership, to use only those pesticides which are registered by the responsible authorities of both the State and Federal Governments and to use such materials in a manner described by the manufacturer's registered label and as recommended by the professional authorities in our field.

I provided to you in my statement a list of the major concerns that we have in terms of the administration of the FIFRA Act by EPA during the period of 1978 up to the present time. I have listed five particular issues. The first one is the lack of observance of State primary enforcement authority for pesticide use. This issue, as I indicated, is one that has been included and discussed at length by representatives from Orkin and Terminix.

The next issue is the failure to revise the FIFRA civil penalties enforcement procedures and their schedule of fines.

The 1978 FIFRA amendments continued EPA's early authority to issue warnings for certain offenses without fines. The act states that the gravity of the offense is to be considered in assessing fines. In addition, section 14(a)(2) was amended in 1978 to provide that persons providing pest control services are subject to a maximum penalty of \$500 for the first offense and \$1,000 for subsequent offenses.

We have had reported to us instances of EPA imposing maximum penalties based on the 1974 schedule.

The statement goes into detail in terms of describing the significance of this particular issue. We would like to see the 1978 FIFRA amendments implemented as they relate to civil penalty practices and the scheduled fines. As of this date, the regulations have not been written for these two sections.

The third concern are the exceptions that are being made by EPA pesticide use regulations in at least one Federal agency program.

The Reorganization Plan Number 3 designates EPA as the national authority to regulate the use of pesticides. Thus, the decision on use instructions that appear on the pesticide labeling is the responsibility of EPA. This Agency is expected to take into consideration the potential for harm to humans and to the environment for approved uses jointly with the other Federal establishments with authority for protection of our food supplies from contamination by pesticides or other foreign substances.

The structural pest control industry provides services to protect our food supply, as I have indicated, whether it is in the processing, storing, or whether it is being served.

One agency, the USDA meat and poultry inspection program—MPIP—has decided that the label instructions will not apply to their

facilities without observance of a separate set of use instructions. Regardless of the lack of evidence to indicate any contamination from the use of pesticides in the meat and poultry plants by structural pest control operators, a separate manual of pesticide use instructions has been developed and placed in operation requiring supervision in the application of pesticides by personnel who are not trained in this field.

Obviously, there is duplication, and there are inconsistencies and, as a result of this, there has been some instances of very poor pest control.

This exception to the EPA label uses has increased potential for confusion by the PCO as to whether the label instructions can, in fact, be followed in a USDA plant even though it is considered appropriate in other food preparation facilities.

The USDA, I am very happy to report, has acknowledged the need for cooperative action with the pest control industry to assure maximum effectiveness in pest control and a minimum chance of hazard for pesticide contamination in the Nation's meat and poultry plants.

Within the past month we have met with representatives of the meat and poultry inspection program and gotten their agreement on some changes that will tend to be based on advanced planning for pest control management in the meat and poultry plants. I believe we are very close to reaching agreement on ways of reducing the confusion that has existed over the past few years so that we can both do the job that we are best qualified to do. We will keep the committee informed of progress with USDA on this matter.

The fourth concern deals with the EPA requirements of applicator recertification and testing.

With your permission, Mr. Chairman, I would like to focus on this particular issue today.

Section 4 of FIFRA does not contain a requirement that certified applicators be retested periodically to determine their continuing competence to apply restricted use of pesticides. Retesting was developed by EPA as an extra provision through regulation to implement the FIFRA section on certification.

Section 4 of the 1978 amendment states that:

The Administrator shall prescribe standards for certification of applicators of pesticides. Such standards shall provide to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of a pesticide or class of pesticides covered by such individuals' certification

In August 1979, EPA published in the Federal Register its "Statement of Policy on Recertification by Training of Commercial Applicators in Colorado and Nebraska Under the FIFRA, as Amended." Colorado and Nebraska, as you are well aware, are two States which have said, "no thank you," to the EPA in setting up and carrying out an elaborate administrative process for pesticide use regulation including the certification of applicators. As a result, EPA carries out the responsibility for certification in those States.

In the above EPA statement there also appears the following provision:

Final regulations (40 CFR 171.11) provide that a certified commercial applicator may qualify for recertification by taking and passing written examinations administered by EPA, *or by successfully completing an EPA approved training course.* [Emphasis supplied.]

The subsequent fine print of this Federal Register statement, however, provides no alternate to the testing provision. The PCO must take a written test in either case. Structural pest control operators find this requirement excessive.

Experience in fields requiring more extensive professional training than pest control demonstrates that certification, and specifically passing of written tests, does not assure competent performance. In our field, there are some competent operators who have learned their practices from observation and on-the-job training. They can read, but they do not depend on reading the Federal Register or scientific papers as to what is new in their field. They keep up to date by attending training courses that are sponsored by their professional association or by the State lead agency in pesticide regulation.

I think it is significant that in a statement on certification requirements that was published in the Federal Register in 1975, EPA stated: "That continuing training programs may well be preferable to re-examination." Also, that:

Properly conducted training programs concurred with and periodically reviewed by the state lead agency may be an effective method for assuring that applicators continue to meet these requirements.

The structural pest control operators represented by NPCA support the policy of continuing education training to update operators in changing technology and on new Federal requirements concerning restricted use pesticides.

This industry has vigorously supported the appropriation of increased State and Federal funds for applicator certification and continuing education training. Our industry does not support the need for written tests to periodically reaffirm that they know what they were confirmed as knowing when they were initially certified. This is a make-work arrangement for the Government. It is also, in our view, reaching beyond what is provided for in the law.

The EPA requirements for recertification by training and testing in Colorado and Nebraska were recommended by EPA for adoption in other States with approved EPA programs. It is significant to note that few, if any, other States have such a requirement. We consider the EPA testing requirement punitive, unnecessary, and contrary to the best interests of cooperative support from the pest control operators for the delivery of safe, up-to-date and effective pest control services.

Mr. Chairman, my final concern deals with the subject of EPA decisions on pesticides not scientifically based.

We are concerned with the pattern of EPA decisions banning or restricting pesticides without appropriate documentation from scientific studies.

In the decisions made to date there is inadequate recognition by EPA of the safety and benefits from the long-term use of certain pesticides. Some of these pesticides have been questioned by EPA primarily on the basis of media reports or from slanted case histories from persons devoted to reducing the use of all pesticides or certain chemicals in areas that they have a claim on for personal uses.

There appears to us to be a rush by EPA by pattern to spend millions of dollars to ban substances without proof of any significant hazard and for which there is not a substitute comparably effective or

as safe. There appears to be minimal, if any, confirmation from the scientific community for many of the decisions that have been made by EPA. The decision not to permit the use of chlordane against powder post beetles and wood borers is one example that affects the structural pest control industry.

For the record I think it is important to note that NPCA is committed to the reduction in the risks to health of pest control operators and the general public. We believe, however, that the determination of hazards must include the assessment of risks to humans and be based on data that is developed and evaluated by a properly constituted group of scientists without concern for regulatory action.

A summary of the recommendations on these points might be worth mentioning for Mr. Fithian's benefit, who just arrived. They are on page 11, Mr. Fithian.

The National Pest Control Association urges the following action by the committee:

One: A review of EPA enforcement operations to eliminate duplication and usurpation of State enforcement authority and to insure compliance with the 1978 FIFRA amendments.

Two: Consideration of ways to speed up the EPA issuance of rules and regulations on civil penalties procedures and a schedule of fines that is consistent with the law.

Three: Elimination of EPA excessive regulations relating to certified applicator recertification content and process, especially in Colorado and Nebraska and other States where they have direct responsibility.

Four: Adoption of requirements for EPA to use the best scientific data available when faced with making decisions to ban or to restrict pesticides, with due consideration given to tradeoffs of human and environments as well as the risks involved.

Finally, we support authorization of FIFRA extension on a 1-year basis in order to monitor the Agency's decisions and action for their consistency with the law that has been passed.

Thank you for providing us an opportunity for sharing our experience and viewpoints, and I will be happy to respond to any questions that you may have.

Mr. DE LA GARZA. Thank you very much, Mr. Grimes.

Without objection, your entire prepared statement will be placed in the record.

[The prepared statement of Mr. Grimes, as well as the supplement, follows:]

SUMMARY OF TESTIMONY by

A. Jack Grimes
 Director of Government Affairs
 National Pest Control Assn.

To the: Subcommittee on Investigations, Oversight & Research
 House Committee on Agriculture

April 15, 1980

A pooling of member experiences and viewpoints on FIFRA implementation by EPA during 1978-80 provides the following observations:

1. There is a lack of EPA observance of state primacy enforcement authority for pesticide use
2. There is failure to revise the FIFRA Civil Penalties enforcement procedures and schedule of fines
3. There is confusion resulting from exceptions by the USDA Meat & Poultry Program to EPA labeled uses of selected pesticides. (We are optimistic negotiations can resolve this soon)
4. There is inappropriate EPA requirement for certified applicator recertification testing in Colorado and Nebraska
5. EPA decisions on pesticides are not always scientifically based. There is a disregard of scientific advice and the necessary balance of benefits versus risks from pesticide uses.

NPCA represents the structural pest control industry nationwide. We wish to conduct our business according to the law and in a manner that protects our own health and that of the public and the environment from pesticide hazards.

To do this we propose a working relationship with EPA in carrying out FIFRA that is reflected in consultation in the planning stages of Agency proposed rules that affect our industry.

We support a one year extension of FIFRA to provide closer monitoring of EPA action in carrying out this Act consistent with the 1978 amendments.

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Mr. Chairman & Members of the Committee:

My name is Jack Grimes. I am Director of Government Affairs for the National Pest Control Association. NPCA is the national membership association of owner/operators of structural pest control companies in the United States. Our membership includes the associations in structural pest control at state and local levels.

Structural pest control is concerned with identifying and controlling pests that invade our homes, offices, factories and warehouses. This industry is the Nation's defense against economic and aesthetic losses from all species of organisms that infest building structures or their contents. Our members also fight the battle to keep our food supplies free of contamination from pests once food leaves the field. Structural pest control operators work to reduce the losses of the nation's food supplies from pest infestations during storage, transportation, processing and distribution up to the time it is consumed. We protect the public's health from pests that serve as carriers of filth and disease as well as from organisms that are common nuisances such as ants, spiders, and scorpions.

The structural pest control industry has used integrated pest management for many years. It has not and does not now depend exclusively on pesticides for effectiveness in its work, although pesticides are an important resource for eliminating and controlling certain infestations. The members of this industry depend primarily upon their knowledge of pest biology and behavior and their experience with a diversity of control methods appropriate for the site rather than dependence upon pesticides likely to be hazardous to them or their customers. We estimate that 95% of pesticides used in our industry are the same ones approved for use by the general public.

On behalf of NPCA and its members, I thank the Committee for this opportunity to present our experience in working with pesticides under the provisions of the current FIFRA. My comments today will focus on member concerns with EPA administration of the 1978 FIFRA with particular attention to the Agency' action in carrying out the law. I will share the members' recommendations on EPA actions that we see as inconsistent with the 1978 amendments and which create problems for the industry and the Agency in doing their work safely and effectively in the public's interest.

In the early 1970's NPCA supported the legislation which gave the EPA authority to regulate the use of pesticides. The Association actively supported EPA approved programs of certification of persons who apply, or supervise technicians in applying, pesticides classified by EPA and the states for "restricted use". It is and has been the policy of NPCA, and thus its membership, to use only those pesticides which are registered by the responsible authorities of state and federal governments and to use such materials in a manner described in the manufacturer's registered label and as recommended by professional authorities in our field.

For your oversight purposes today, I will describe briefly five areas of concern (see summary sheet) in EPA's administration of FIFRA for the structural pest control industry:

1. Lack of Observance of State Primary Enforcement Authority for Pesticide Use
(FIFRA Sections 26 and 27)

Under 1976 and 1978 FIFRA amendments, increased enforcement authority is transferred from EPA to those states submitting a program that satisfies the EPA criteria for primary enforcement responsibility. Section 26 (d) states that:

"Any state that has a plan approved by the Administrator (EPA) in accordance with requirements of Section 4 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have primary enforcement responsibility for pesticide use violations."

EPA is directed in this part to make determinations with respect to state plans not later than March 31, 1979. Our industry is pleased with the Administrator's action in recognizing most state plans and also in assisting the few states not meeting the criteria by March 1979 to do so as quickly as possible. Our industry supports the concept of state enforcement primacy in the interest of increased safety and effectiveness in monitoring and supervising pesticide use. Regulatory authorities in the states are as much if not more concerned with the human and environmental safety in their state as EPA and we feel they are likely to take regulatory action jointly with the parties to be regulated in their state to see that the job is done appropriately. In addition to the increased effectiveness and sensitivity that is possible from state action, which this Committee recognized early, it is, we believe, more cost effective than a Federally administered enforcement program.

Of concern to us in EPA's implementation of the state primacy concept is the lack of observance in practice of Section 27 (b) which states:

"Whenever the Administrator determines that a state having primary enforcement responsibility for pesticide use violations is not carrying out such responsibility, the administrator shall notify the state. Such notice shall specify those aspects of the administration of the state program that are determined to be inadequate. The state shall have 90 days after receipt of the notice to correct any deficiencies".

Subsection (a) of this section, requires EPA to refer any violation complaints to the state officials for investigation. Thirty days are given to the state to commence appropriate enforcement. If this isn't done, the administrator may act on the complaint, with notice given to the state, of EPA intent to take action in that state. The full procedure for EPA to follow is given in Subsection (b) as cited above. As recently as last month, we have had reported to us an

enforcement action by EPA personnel in states with enforcement primacy. Also, in other states across the country over the past year, we have received reports of enforcement inspectors operating under dual authority of both the state regulatory agency and the EPA. Additional information will be provided to you by the representatives from Orkin and Terminix, International on this dual enforcement problem for their pest control firms which are the largest in the field.

We brought the occurrence of the inappropriate enforcement procedure to EPA's attention last April and then again in June of 1979. I am pleased today to report that on March 4, 1980, a "clarification" was mailed by EPA to their Branch and Regional offices, outlining what appears to be enforcement procedure more consistent than past action with the above cited provisions of the law. I hasten to add however, that we still have questions about some of the instructions covered in the March 4 memo. We were not advised before or after this memorandum was issued. We learned about it indirectly. NPCA, as one of the parties significantly impacted by the decisions made in this EPA memorandum, felt it only appropriate to be notified of its contents. We would prefer to have been consulted in advance about the contents to help insure clarity of points of concern to our industry. No regulations have been issued by EPA for FIFRA Sections 26 and 27 as of this date. Since issue of the March 4, 1980 clarification memo, we continue to receive reports of EPA enforcement officials taking action in states that have been given prime enforcement authority. It is our viewpoint that this type of dual enforcement action is contrary to the provisions of FIFRA as amended in 1978.

2. Failure to Revise FIFRA Civil Penalties Enforcement Procedures and Schedule of Fines (FIFRA Section 14)

The 1978 FIFRA amendments continued EPA's early authority to issue warnings for certain offenses without fines. The Act states that the gravity of the offense is to be considered in assessing fines. In addition, Section 14 (a) (2) was amended in 1978 to provide that persons providing pest control services are subject to a maximum penalty of \$500 for a first offense and \$1,000 for subsequent offences.

We have had reported to us instances of EPA imposing maximum penalties in citing violations of minor gravity to human health or to the environment, and in 1979 imposing maximum penalties based on the 1974 schedule.

In our discussions of this situation with the staff at EPA Office of Enforcement, we detect an attitude, which is supported by EPA actions, that a financial penalty is the best deterrent against misuse whether it be inadvertent and reflecting a minor threat to others. Efforts by my office to encourage receptivity to our experience with these EPA actions have been answered by the statement "that the civil penalty procedure and the schedule of fines are intra-agency procedural documents and as such EPA is not required to work with anyone developing them until published in the Federal Register for comment." If we had comment or criticism, we were invited to supply it for the record. Because of this authoritarian, punitive philosophy, revision of the EPA civil penalties practices and penalty amounts has been occurring at a glacial pace. Actions have been announced for developing the revision on two separate occasions, but in each instance the action was postponed "because of other priorities".

NPCA supports the need for financial penalties for significant misuse of restricted use pesticides. Where misuse is the result of intent or carelessness,

a fine is in order. However, if due care is taken and the gravity of the offense is minor, we agree with this Committee's decision that a warning is more appropriate. It is a growing belief in our industry that the EPA penalty assessment practices have done little to encourage a cooperative and receptive attitude towards enforcement inspections and the opportunity such occasions provide for improving pesticide use practices. In any event, we at NPCA believe the law should determine EPA enforcement policy. This hasn't been observed in all instances to date. The testimony of the representatives from Orkin and Terminix today may provide additional detail on the effects that the above described enforcement attitude by EPA has had on encouraging similar action by state enforcement authorities. We would like to see the 1978 FIFRA amendments implemented as they relate to civil penalty practices and scheduled fines.

3. Exceptions are Being Made to EPA Pesticide Use Regulations In At Least One Federal Agency Program

The Reorganization Plan #3 designates EPA as the national authority to regulate the use of pesticides. Thus, the decision on use instructions that appear on the pesticide labeling is the responsibility of EPA. The Agency is expected to take into consideration the potential for harm to humans and the environment for approved uses jointly with the legally established authority of other federal agencies such as the Food and Drug Administration and the U.S. Department of Agriculture, both concerned with the safety of food from contamination by pesticides or other substances.

The structural pest control industry provides services to protect against pest contamination where food is prepared, packaged, processed, stored or served.

One agency, the USDA Meat and Poultry Inspection Program (MPIP) has decided that the label instructions will not apply in their facilities without observance

of a separate set of use instructions. Regardless of the lack of evidence to indicate any contamination from the use of pesticides in the Meat and Poultry Plants by structural pest control operators, a separate manual of pesticide use instructions has been developed and placed in operation requiring supervision in the application of pesticides by personnel who are not trained in this field. Duplication, inconsistencies and poor pest control have developed as a result. This exception to EPA label uses has increased potential for confusion by the PCO as to whether the label instructions can be followed in a USDA plant even though it is considered appropriate in other food preparation facilities. The USDA has acknowledged the need for cooperative action with the pest control industry to assure maximum effectiveness in pest control and minimum chance of hazard from pesticide contamination in the nation's meat and poultry plants.

I am happy to report that the USDA MPIP is currently working with the National Pest Control Association to develop pest control procedures for the MPIP plants so that the EPA label uses prevail and the pest control operators skill in planning and applying pesticides is respected. The objective for this program is advance pest management planning jointly with the plant manager and the MPIP inspector, so that the need for the use of pesticides is prevented and when a pest infestation does occur, it becomes a signal for the occurrence of inadequate sanitation or the need for possible building repair in order to exclude the entrance of pests into the food processing area.

This program is still under development with the USDA. We are optimistic, however, for a successful result in the near future because it is being developed with the realization that safe pesticide use by the pest control specialist is essential in these plants. We are also optimistic because there is joint agreement between our industry and the USDA on the need for less dependence on routine pesticide use and added concern with prevention and control through integrated pest management.

However, if we are not successful in working out a solution with USDA and conditions develop where a specialized set of pesticide use rules for each Federal agency becomes a requirement for the members of our industry, we will defeat the purpose of FIFRA in having a single agency with the responsibility for determining pesticide use rules. We will keep the Committee staff informed of progress with the USDA on this matter.

4. EPA Requirements of Applicator Recertification and Testing (FIFRA Section 4)

Section 4 of FIFRA does not contain a requirement that certified applicators be retested periodically to determine their continuing competence to apply restricted use pesticides. Retesting was developed by EPA as an extra provision through regulation to implement the FIFRA section on certification. Section 4 of the 1978 amendments states that:

"The Administrator shall prescribe standards for certification of applicators of pesticides. Such standards shall provide to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of a pesticide or class of pesticides covered by such individuals' certification..."

In August of 1979, EPA published in the Federal Register its "Statement of Policy on the Recertification by Training of Commercial Applicators in Colorado and Nebraska under the FIFRA, as Amended". Colorado and Nebraska are two states which have said, "no thank you" to EPA in setting up and carrying out an elaborate administrative process for pesticide use regulation including the certification of applicators. In the above EPA statement, there also appears the following provision:

"Final regulations (40 CFR 171.11) provide that a certified commercial applicator may qualify for recertification by taking and passing written examinations administered by EPA, or by successfully completing an EPA approved training course" (underlining added)

The subsequent fine print of this Federal Register statement, however, provides no alternate to the testing provision. The PCO must take a written test in either case. Structural pest control operators find this requirement excessive. Experience in fields requiring more extensive professional training than pest control demonstrates that certification, and specifically passing of written tests, does not assure competent performance. In our field, some competent operators have learned their practices from observation and on the job training. They can read but they do not depend on reading the Federal Register or scientific papers as to what is new in their field. They keep up-to-date by attending training courses offered by their trade association or reading releases as to appropriate developments in their field that are issued by their employer, their trade association, and the state lead agency.

In a statement on certification requirements, published in the Federal Register earlier (March 17, 1975) EPA states:

"That continuing training programs may well be preferable to re-examination"

Also, that --

"Properly conducted training programs concurred with and periodically reviewed by the state lead agency may be an effective method of assuring that applicators continue to meet these requirements."

The structural pest control operators represented by NPCA support the policy of continuing education training to update operators in changing technology and on new federal requirements concerning restricted use pesticides. This industry has vigorously supported appropriation of increased state and federal funds for applicator certification and continuing education training. Our industry does not support the need for written tests to periodically reaffirm that they know what they were confirmed as knowing when initially certified. This is a make work arrangement for the government. It is also, in our view, reaching beyond what is provided for in the law.

The EPA requirements for recertification by training and testing in Colorado and Nebraska were recommended by EPA for adoption in other states with approved programs. To date, few if any other states have such a requirement. We consider the testing requirement, punitive, unnecessary and contrary to the best interests of cooperative support from the pest control operators for the delivery of safe, up-to-date and effective pest control services.

5. EPA Decisions on Pesticides Not Scientifically Based

We are concerned with the pattern of EPA decisions banning or restricting pesticides without appropriate documentation from scientific studies. In the decisions made to date there is inadequate recognition by EPA of the safety and benefits from the long term use of certain pesticides. Safety of some pesticides has been questioned by EPA primarily on the basis of media reports or from slanted case histories from persons devoted to reducing the use of all or certain chemicals in areas used for personal objectives. There appears to us to be a rush by EPA to spend millions of dollars to ban substances without proof of significant hazard and for which there is not a substitute comparably effective or as safe. There appears to be minimal if any confirmation from the scientific community for many of the decisions that have been made. The decision not to permit use of chlordane against powder post beetles and wood borers is one example affecting our industry.

NPCA is committed to a reduction in the risks to the health of pest control operators and of the general public. We believe however, that the determination of hazards must include the assessment of risks to humans and be based on data that is developed and evaluated by a properly constituted group of scientists without concern for regulatory action.

RECOMMENDATIONS

The National Pest Control Association urges the following action by the Committee:

1. Review of EPA enforcement operations to eliminate duplication and usurpation of state enforcement authority and to assure compliance with the current law.
2. Consideration of ways to speed up EPA issuance of rules and regulations on civil penalties procedures and a schedule of fines that is consistent with the 1978 FIFRA amendments.
3. Elimination of EPA excessive regulations relating to certified applicator recertification content and process, especially in those states where this activity is the direct responsibility of the EPA.
4. Adoption of requirements for EPA to use the best scientific data available when faced with making decisions to ban or to restrict pesticides, with due consideration given to trade-offs of human and environment benefits as well as risks.
5. Authorization of FIFRA extension on a one year basis in order to monitor the agency's decisions and action for their consistency with the law.

The structural pest control industry supports the current FIFRA provisions. We are concerned with the resistance by EPA to consulting early in rule development with the parties significantly affected by their decisions, especially the structural pest control industry.

Thank you for providing us the opportunity to share our experience and viewpoints on FIFRA with you.

I will be happy to respond to questions you may have.

NATIONAL PEST CONTROL ASSOCIATION, inc.

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May 7, 1980

Rep. E. de la Garza
Chairman, Subcommittee on Department Investigations
Oversight & Research
House Committee on Agriculture
U. S. House of Representatives
Washington, D. C. 20515

Dear Mr. Chairman:

After hearing EPA's testimony before your committee on May 1 and after a careful study of the written statement, it is obvious that a portion of my statement to the Oversight Hearings on EPA Administration of FIFRA, needs clarification and amplification. As a result it is my hope that you will have this supplement to NPCA's statement inserted into the record.

One of the concerns we listed in EPA's implementation of the 1978 FIFRA amendments is their inappropriate regulations in Colorado and Nebraska that specify a variety of options for recertification through continuing education training, all of which call for some form of written or verbal testing (See Item 4, page 8 of our 4/15/80 testimony). The EPA's reply to our statement of concern appeared in Mr. Jellinek's testimony of May 1. He did not respond to the inappropriate testing provisions in the continuing education courses but confuses our concern with whether PCO's are choosing to be recertified by written exam or continuing education courses. No response is provided to our question about no alternative actually being provided in the published rules for recertification that does not call for written or participation test responses.

Contrary to the view expressed by Mr. Jellinek, NPCA is aware of "what is actually happening in the field", particularly in Colorado and Nebraska. We do know from reports from structural pest control operators that EPA's Mr. Johnson and Mr. Combs in Colorado and Mr. Wicklund and Poindexter in Nebraska have demonstrated perception, understanding and flexibility in developing acceptable procedures which place less emphasis on testing. These gentlemen are to be commended for their effort. We are pleased that, as a result, those states "do not have a problem".

The objective of our April 15 testimony, however, was not to deal with the effectiveness of current procedures developed in those states. Our purpose was to emphasize our concern with the rules themselves. While the rules do provide for recertification by continuing education, they also call for an individual to prepare worksheets which "...include problems and questions..." and requests "each attendee to analyze and answer questions." In addition "worksheets should be completed on an individual basis." Finally "an EPA official will be responsible for reviewing each participants worksheet to insure that the individual fully participates in the course and completes all course requirements." In effect that is testing, particularly in view of the

specific statement in the regulations that "mere passive attendance...will not be considered as successful completion. Each of the four Applicator participation Options include requirements which can be construed as testing.

Since EPA is apparently recommending these rules to other states for their recertification procedures we want to reiterate our concern with the prescribed testing provisions which are an integral part of the EPA rules for continuing education for recertification. We have no assurance that these rules as written, subject as they are to the interpretation by the individuals implementing them, will be similarly interpreted by regulators in other states which may eventually adopt these procedures. We want the rules amended so that it is clear that a previously certified PCO does, in fact, have the clear choice of passing a written test for recertification or attending approved continuing education courses without also having to pass another set of written and/or verbal tests as a review on the basic skills that he was previously tested on when he received his initial certification.

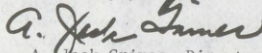
As cited in our testimony, our requested change is consistent with recertification procedures that are now in successful operation in most of the other states under approved EPA programs. That is the reason "the overwhelming majority" of the PCO's have been recertified through continuing education as cited in Mr. Jellinek's comments of May 1. Our recommendation on this is also consistent with the EPA published comments on the procedures for recertification that were published in the Federal Register of March 17, 1975.

Our final point on this specific subject relates to the 1981 budget request submitted to Congress by EPA on January 28, 1980 for carrying out the certification and recertification regulations. The EPA budget request states that EPA will incorporate applicator certification activity into the pesticide enforcement program. We are concerned that the recertification through continuing education with the testing provisions may be stringently applied to our industry. Most other states in our nation agree that the alternative to passing a written test for recertification is participation by commercial PCOs in continuing education courses meeting the EPA criteria but without written or verbal testing.

We plan to continue to explore the revision of the recertification rules for Colorado and Nebraska with EPA personnel at the Federal and Regional levels so that there is in fact by the rules a valid choice for either taking a written test or participating in approved continuing education courses. We appreciate the opportunity for providing this additional information on the EPA trusteeship in carrying out the FIFRA authorities this year.

The National Pest Control Association supports HR 7018 providing FIFRA authorization through September 1981.

Sincerely yours,



A. Jack Grimes, Director
Government Affairs

AJG:st

cc: EPA - Douglas Costle
Steve Jellinek

MR. DE LA GARZA. Mr. Fithian?

MR. FITHIAN. I just have one question. After talking to several of the earlier witnesses this morning, Mr. Chairman, and discussing the question that you raised toward the end of your testimony—that is, to develop some kind of informal consultation between industry and the EPA, do you have any particular structural suggestion in mind?

MR. GRIMES. None beyond what is already provided for. We would like EPA when they have an issue that significantly impacts on our industry, to call us or write us and say:

Look, we would like to have your comments, suggestions, and thoughts on this so that we can start with a practical experience of the industry in that area.

MR. FITHIAN. That is pretty much absent now?

MR. GRIMES. We do not find that happening. I cite in my testimony the case where we were particularly interested in the civil penalties provisions. We shared with them last April a request—we were bringing some sad experiences on what was happening in the field. We did it again in June, and there was no response. We finally got a note back from the enforcement office saying that this is an intragency concern, and that they thus felt it was only necessary to invite criticism once they put it in the Federal Register.

I do not consider that a particularly instructive approach to getting the fastest and the best constructed recommendations out in this field. We would like to see it happen in more areas more often.

MR. FITHIAN. Thank you, Mr. Grimes. Thank you, Mr. Chairman.

MR. DE LA GARZA. Mr. Wampler?

MR. WAMPLER. Thank you, Mr. Chairman.

MR. GRIMES. I apologize for being tardy. I was in a meeting in my office with some representatives from the Rural Electrification Administration.

I noted, however, on page 10 of your statement where it deals with EPA decisions on pesticides not being scientifically based—I want to assure you that that I share those concerns. I don't know whether you heard the testimony this morning, but I did ask some of the witnesses this morning their reaction to some legislation that I have introduced which, in effect, would set up an independent scientific board to make the scientific determinations for these various regulatory agencies, including EPA's jurisdiction over FIFRA.

I agree with you, and in your recommendation No. 4 you state:

Adoption of requirements for EPA to use the best scientific data available when faced with making decisions to ban or to restrict pesticides, with due consideration given to tradeoffs of human and environment benefits as well as risks.

I think this is something that we are going to have to do and, unfortunately, there are many who feel that we should live in a risk-free society. I do not think that faces reality very well, and I think there has to be a trade-off somewhere. This committee is deeply concerned with protecting the environment against undue harm or against harm to human health.

Do you not agree that there is a better way for us to make these scientific determinations rather than permitting an agency of the Government to many times act in what at least some of us think is a rather precipitous way and without solid scientific data on which to make those determinations?

Mr. GRIMES. We agree with you wholeheartedly. In fact, they even ignore some of the scientific advice they do have access to. That has been our experience.

We agree with the concept and philosophy that you have embodied in the bill that you are proposing, Mr. Wampler, and we will be forthcoming with some recommendations on the suggestions that you have in that bill.

Mr. WAMPLER. I appreciate that, and I would be happy to receive them. Thank you.

Mr. DE LA GARZA. Mr. Fithian?

Mr. FITHIAN. Thank you, Mr. Chairman.

Would you just summarize in a word or two your experience with the Scientific Review Panel now created as a part of the 1978 FIFRA?

Mr. GRIMES. We have had practically none in terms of experience in meeting with that group. What they have on their agenda is consideration of topics that will impact on our industry. We will go, but we have found in a few instances that even with the recommendations from the Scientific Advisory Panel that they now have that they are disregarded. So that may not be a very constructive use of our time because it does not seem to carry any weight.

Mr. FITHIAN. So you feel that regardless of the qualifications and activities of the Panel, that their scientific perspective is not transmitted through and does not become part of the EPA process?

Mr. GRIMES. It is not being taken and respected in terms of the recommendations that they have, that is, the Scientific Advisory Panel is not being utilized.

Mr. FITHIAN. The reason I raise the question is this. As I see Mr. Wampler's legislation—I have not had a chance to study the bill—that would be an admission that we need something, from your point of view, much stronger than the Scientific Review Panel. It would be something with more clout or authority or some such thing.

Early on, when we offered the amendment to create the Scientific Review Panel in 1977, it was with the thought of addressing this same question and the same problem that Mr. Wampler's legislation would now address. That is why I was wondering from the industry's point of view, whether the Scientific Review Panel had really the kind of impact that we had hoped it would have when we created it.

Mr. WAMPLER. As far as I am concerned, I think the Scientific Advisory Panel has been composed of very competent individuals. They have been very diligent in carrying out their responsibilities. But, I agree that the problem has been that the Agency has not adhered to the recommendations or has not given them adequate consideration. I am not saying that they have ignored them, but I just do not think they have taken it as we intended it here in the committee.

Mr. GRIMES. I agree with you, Mr. Wampler.

Mr. WAMPLER. The purpose of my bill would be that this National Science Council would actually make the scientific determination which would be binding on the regulatory agency. That would be the determination. It is binding. While the bill is not perfect, we think this is a better approach and the one that deserves a good deal of discussion and, hopefully, we can get the dialog started and maybe in the next Congress we can have hearings on it and see what kind of reaction we get. I thank the gentleman for yielding.

Mr. DE LA GARZA. If there are no further questions, we thank you, Mr. Grimes, for your testimony.

Yours, and all the previous testimony of today, will be analyzed hopefully by all the members of the subcommittee.

A hearing is scheduled for May 1, to accommodate Mr. Costle from EPA.

I might explain publicly that the basic reason for that was Mr. Costle's inability to be with us today. Because of conflicts with subcommittee, committee, or with Mr. Costle, the earliest possible date was May 1; it was for that and no other reason.

One of the reasons that the decision was made to continue for his testimony and not invite those who have already presented testimony is because it could lead to a roundrobin—never ending. But I want to assure you on the record, that all those who have legitimate concern and those who testified that all of those concerns will be presented to Mr. Costle. Should there be someone who feels that the world will not turn the next day unless he has the ability to rebut, we might allow in certain circumstances that to be done.

With that, the subcommittee will adjourn until we continue with this legislation on May 1.

[Whereupon at 2:35 p.m., the subcommittee was adjourned.]

[Supplemental material submitted follows:]



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State of North Carolina 1980 APR 21 AM 11:12

Department of Agriculture OFFICE OF
HONORABLE THOMAS S. FOLEY

Raleigh

JAMES A. GRAHAM
COMMISSIONER

April 15, 1980

Honorable Thomas S. Foley
Chairman
House Agriculture Committee
1301 Longworth Office Building
Washington, D. C. 20515

Dear Congressman Foley:

In light of the present oversight hearings with EPA I wanted to relate to the House Agriculture Committee some recent difficulties between EPA and the State of North Carolina in pesticide enforcement. Our state was one of the first states to enter into a pesticide enforcement agreement with EPA and over the years has been recognized as having an effective pesticide program.

In three incidences of technical misuse of pesticides the state took what it considered appropriate action. The evidence of record was not sufficient for the Attorney General of North Carolina to feel that a suspension or revocation of the pesticide applicator's license would be upheld in court. There had not been a previous problem with these companies in regard to chemical misuses in North Carolina. Considering these pertinent facts the state took a position of warning rather than imposing a severe penalty.

The regional EPA office in Atlanta chose to apply an additional civil penalty on the three cases without the state even being notified of such action. We were told by EPA that program audit people from the Office of Management and Budget had indicated that there should be more civil penalties levied by EPA. In general, state enforcement agencies do not have legal authority to levy civil penalties. These agencies do; however, have the capability of revoking or suspending pesticide applicators licenses. In approving states for enforcement agreements EPA recognizes and accepts each states capability to enforce FIFRA. When questioned about the action taken in the above cases, EPA officials indicated that other states had not complained. This leads one to believe the usurping of the states primacy in pesticide enforcement had been a routine

Honorable Thomas S. Foley
Page 2
April 15, 1980

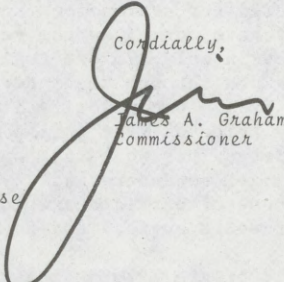
philosophy. This we felt was not the intent of Congress.

After extensive efforts by Congressman Rose and others, EPA did recognize the problem that was being created by adding additional penalties after the state had taken what it considered appropriate action.

I believe that Congress and the states feel that states with EPA enforcement agreements can and will take appropriate enforcement actions. This agency certainly will be accountable for its action and does not hesitate to present its reasoning. If states are to be able to do a good job of enforcement they must be able to have the feeling of primacy without constant intervention. Where EPA sees a truly hazardous situation and feels it is not properly addressed, further action should be taken. We trust that Congress will insure that such action would be with the full understanding of the States involved.

Congress has made its feeling clear that pesticide enforcement should be done at the state level. In order to result in meaningful enforcement the states must be able to develop a certain firm, but fair rapport with the regulated industry. The recent direction of EPA in enforcement philosophy was definitely not conducive to this development. This agency feels and believes that your committee expects EPA to honor the states primacy in pesticide enforcement. The current change in direction of EPA seems to recognize this fact, at least in part. We trust your hearings will assure that this direction will continue.

Cordially,


James A. Graham
Commissioner

JAG:ab

cc: Congressman Charles Rose
J. B. Grant, NASDA
John Stackhouse
William A. Wilder, Jr.

STATEMENT OF
AMERICAN ASSOCIATION OF NURSERYMEN

BEFORE

SUBCOMMITTEE ON
DEPARTMENT INVESTIGATIONS, OVERSIGHT AND RESEARCH
HOUSE COMMITTEE ON AGRICULTURE

The American Association of Nurserymen is a national trade association with approximately 3000 member firms involved in the production, wholesaling and retailing of trees, shrubs and vines used for commercial fruit production, home garden production, and landscape and environmental improvement of our homes, churches, schools, businesses, highways, parks and forests. Our members are producing more than 2000 species of plants in commercial trade. On one hand, the State and Federal Departments of Agriculture require that these living plants be free of hazardous insects and diseases before they enter and remain free while in the channels of commerce. This means that in addition to the incentives common in all of agriculture to produce agricultural crops which are healthy and vigorous, by regulatory requirement nurserymen have very specific pesticide needs to meet these regulatory requirements.

Because of EPA's interpretation of FIFRA, we are still having difficulty obtaining pesticide registrations for nursery use on non-edible plants. The nursery use registrations needed are for pesticides already registered for use on food and feed crops. The 1978 amendments helped some but have not given the relief needed. Since 1977, we have been able to obtain only 473 use registrations for ten pesticides. These were obtained through the Interregional Research Project 4. These 473 were from a top priority list of 2000 nursery registration needs that were selected from a list of 7300 needs prepared in 1977. Even these registrations would not have been possible without the 1978 amendments. We fail to understand why crops for nonfood and nonfeed use are denied the use of pesticides which are already registered for the same or similar pests on food and feed crops.

As a result of the 1978 negotiated settlement in the chlordane/heptachlor hearing, a limited quantity of chlordane for specific nursery uses was authorized for manufacture and sale before December 31, 1979. The manufacture and sale of chlordane for nursery uses was terminated on that date. The industry and EPA were led to believe that alternate chemicals would be available to meet quarantine and regulatory requirements by the time the special exemption expired December 31, 1979. This relief has not occurred and EPA indicates that the only way they will consider a possible request for continuation of the special nursery uses of chlordane in the production of nursery crops would be on the basis of substantially new information. The one alternate material registered at this time is the "FA-5" formulation of chlorpyrifos for use in the container or pot production of nursery plants. There is a second label for a different formulation of chlorpyrifos to meet the Imported Fire Ant Quarantine Certification requirements for field grown plants by dipping the balls of earth in which the roots of the plant are growing when the plant is dug "balled and burlapped." In both the aldrin/dieldrin and the chlordane/heptachlor hearings, nursery witnesses have stated that this practice is horticulturally, economically and environmentally unacceptable except for treating a limited number of plants under emergency situations. EPA insists that the new label can be used to meet

the industry needs for field-produced nursery stock. A two-inch caliper shade tree would require a 24-inch "balled and burlapped" root ball. This ball would weigh 310 pounds. The root ball on a three-inch caliper shade tree would need to be 32 inches in diameter and would weigh 750 pounds. The tank, extra crew and equipment needed to dip treat plants would add greatly to production costs. Once the ball of earth had been dipped to absorb the chemical necessary to kill any soilborne insects, it would have to be left sitting for excess absorbed chemical solution to drain from the ball. If dip treating is done on a continuing basis, the accumulation of the chemical in the field set aside for draining would be an absolutely unacceptable environmental practice. Another unanswered question is where and how to dispose of the dip solution remaining in the dip tank after the plants had been treated? Nurserymen who have in the past in emergency situations dip treated small numbers of plants, found the survival rate sharply reduced because of destruction of the soil structure and loss of hair roots. Dipping is not only a last resort solution but unacceptable as a general practice for the reasons previously stated.

Without the continued use of chlordane or an acceptable registered substitute for it, the production from some nursery fields that were not treated or the treating occurred sufficiently long ago that the chlordane has broken down to the extent that the plants are not certifiable for quarantine and regulatory purposes, will become an issue in 1980. The problem will intensify in 1981 and by 1982 only a few fields which were treated in 1979 will remain certifiable and there will be no fields certifiable in 1983 for Japanese beetle, imported fire ant, white fringed beetle, European chafer or black vine weevil. The latest projections we are able to get from USDA research scientists are that it will probably take up to two years for testing and working out application schedules and application procedures for alternate chemicals to chlordane before applying for registrations for uses on nursery crops that will meet the quarantine and regulatory certification requirements.

EPA indicates they are neither endorsing nor supporting the Friends of the Earth which would require 250 foot buffer along the edge of the property being treated without written authorization of the owner of the adjacent property. Representatives of the association have been at two meetings at which EPA officials indicate a buffer zone concept is under serious consideration for adoption. The 250 foot buffer zone for ground applications as proposed would mean that a retail nursery would have to be larger than 1.4 acres in size to be able to have the first square foot of land that they could treat without written permission of adjacent property holders. There is no indication that this same requirement would not apply to homeowners. With this concept, the retail nursery would be unable to treat their plants to maintain them free of hazardous insects and diseases to meet the state requirements. If the homeowner is likewise limited or denied the privilege of treating trees and shrubs on his property, then those pests would build up and become an intolerable source of infestation for adjacent property owners whether they be homeowners or agricultural enterprises such as nurseries.

The Association is dismayed at the lack of objectivity demonstrated by EPA in publishing the Friends of The Earth petition in the Federal Register and the publication and distribution at government expense of the League of Women Voters Education Fund 16-page bulletin "A Toxics Primer."

EPA appears unwilling or unable to move ahead in completing the implementation of the 1972 Act and later amendments. The Association reluctantly endorses a one year extension of FIFRA.

Additional Comments Of
American Association of Nurserymen
Regarding
1980 FIFRA Oversight Hearings

The Association is greatly disturbed to learn of EPA's involvement in and sanction of Rural America and the several regional pesticide forums they are sponsoring across the country. The Association challenges the objectivity that can be obtained in these forums when correspondence such as that of March 31, 1980 (enclosed) is used to stimulate attendance to present "horror stories" to impress the "Feds." As you will note from the program, Steve Jellinek and Ed Johnson were scheduled luncheon speakers for April 21 at the forum held in the Harlingen area in Texas. Also note the suggestive questions in the "Medical and Work History Questionnaire." Documents like these, following our experience in the aldrin/dieldrin and chlordane/heptachlor hearings and the 2,4,5-T cancellations, make us doubt that EPA has a desire to be objective.

It is our understanding that EPA is seeking an appropriation from Congress for funds to proceed with the destruction of the 2,4,5-T and Silvex banned from sale a year ago. We have made inquiry of the EPA budgetary people and were told that they had no information regarding any past allocation or plans to request funds for indemnifying the retail sales outlets, distributors, formulators and manufacturers who turned the pesticides containing 2,4,5-T and Silvex over to EPA. EPA's ban on further sale of these pesticides came last year just as the local retail nurseries and garden supply stores were stocked for the spring season. A high percentage of these retailers are small family-owned businesses who have had their funds tied up for more than a year and are still unable to get any word as to when they may compensated for these products which EPA withdrew from the market.

Inasmuch as both the previous administrators of EPA had conducted extensive reviews of the registration for 2,4,5-T and Silvex, the Association believes that EPA should have carefully reviewed the "new information" before seriously considering the ban. That "new information" continues to be questioned by scientific and statistical specialists familiar with agricultural and forestry problems. EPA continues to be very quick to accept new information providing it will prove their point. Although they're even looking for new data from foreign countries to prove their point, they are reluctant to accept data from a foreign country when it is used in support of an application for registration. For example, EPA is currently reported to be using new European data to support their claim 2,4,5-T and Silvex are public health hazards. A year ago, when reviewing the application for a bacterial inoculant aiding in the control of crown gall on certain fruit and nut nursery plants, data from Australia and Canada, where it has been available for nursery use for several years, was not permitted. Finally, a national label was granted for this naturally occurring bacteria.

While it is agreed the social effects of pesticides should be considered in EPA decisions, we are getting the impression EPA decisions are based on the number of words in print without any scientific evaluation of those printed words.

Subcommittee on Departmental Investigation
Committee on Agriculture

May 1, 1980.

Gentlemen:

The writer, now 81, spent many years in prominent positions enforcing the National Recovery Administration Act and the Robinson Patman Act and later twenty years as counsel for a large food corporation. Recently I have closely observed the E.P.A. where their bloated budget causes them to act irrationally.

During recent sessions of Congress the Administrator of EPA in response to pleas from Mr. Foley and Mr. de la Garza indicated the Agency would use "Common sense" in carrying out their function.

May I cite a recent case. Last year my help was solicited by a very small manufacturer located in the devastated area of the Bronx, N.Y., there he gives employment to sixteen persons of the minority groups. He bottles and sells through grocery chain stores a household cleaner which includes a small amount of disinfectant which was through excusable error allowed to fall to 1.74%. The Agency ignoring the excuse yet saying adverse effects were not probable never the less is seeking to assess a civil penalty of \$1800. Since last June I have spent a great many hours gratuitously in his defense and the Agency has spent many dollars of tax-payer money - all because common sense is still lacking. Your staff has the details.

I appeal to both Committees to forbid expenditure of money where adverse effects are unknown or not probable yet are now subject to fines of as much as \$5000.

Respectfully Submitted,

A.W. De Birny
A.W. De Birny
Friendship, Md. 20758.

STATEMENT

of
 Glenn Gibson, Executive Secretary
 American Honey Producers Association
 P.O. Box 368, Minco, Oklahoma 73059
 Phone -- 405-352-4126

Mr. Chairman, members of the House Agriculture Subcommittee on Department Investigations, Oversight, and Research, we appreciate this opportunity to comment on the proposed legislation to extend the Federal Insecticide, Fungicide, and Rodenticide Act.

My name is Glenn Gibson from Minco, Oklahoma. I am the Executive Secretary of the American Honey Producers Association, a nation-wide organization of honey producers, beekeepers. We have membership in forty-one states.

As we understand it, FIFRA among other things authorizes the Environmental Protection Agency to register and regulate the use of pesticides. As committee members know, bee losses from pesticide use is one of our major problems. Conservatively, we estimate this loss to be approximately \$20 million annually.

JUSTIFICATION OF PUBLIC INTEREST IN THE BEEKEEPING INDUSTRY'S BEE LOSSES

Probably no better justification for a viable beekeeping industry has been written than the foreword by Dr. E.F. Knipling in the U.S. Agricultural Handbook #496. A part of the foreword follows:

"In the past few decades, we have witnessed the development of an array of agricultural chemicals that have helped advance agricultural productivity to a level never before attained. As important as this development has been for the benefit of society, the use of these chemicals has had serious consequences for honey bees and other insect pollinators. Insecticides applied for controlling destructive insects often pose equal hazards to honey bees and to wild bees. Untold numbers of bee colonies are destroyed or weakened each year due to insecticide exposure. The use of herbicides that increase crop yields and production efficiency, that improve our livestock ranges, and improve the appearance of our roadsides, lawns, and parks are a boon to society. But, the use of these chemicals affects the honey bee and our natural pollinators to a degree that is difficult to assess. Moreover, as the demands for more food increase, we can anticipate more intensive monoculture that disrupts the continuity of plants needed to furnish adequate nectar and pollen for bees. In order to meet the future demands for food and living space, there will be fewer 'idle' acres of land. However, these lands do not remain idle so far as pollinators and other beneficial insects are concerned.

"These developments and trends raise a number of questions regarding the future of apiculture. How can the beekeeper, who depends on bees as a livelihood stay in business in the face of such adversities? Will the amateur beekeeper maintain interest and enthusiasm for a hobby if he cannot obtain at least some material reward for his efforts? For decades, thousands of bee

hobbyists assured the presence of large numbers of honey bees throughout our agricultural environments with great benefits to agriculture, and to the home gardener, but with little compensation to the keepers of the bees. What will be the effect on our agroecosystems if this source of bees disappears? Certainly, the nation must give due recognition to the value of the small but vitally important bee industry and take measures to keep it viable. One way to gain full recognition of the importance of this industry is to have a better understanding of the part insects play in plant pollination, which is the objective of this handbook. This treatise on plant pollination by insects should not only be immediate value to the agriculturist but should clearly indicate the value of insect pollinators to our total environment and to our society."

The Department of Agriculture estimated the value of honey bee pollination at \$8 billion in 1975. A tiny percentage of our beekeepers rent their bees to farmers for pollination purposes, but most of the honey bee pollination is done free of charge.

CONTACTS WITH THE ENVIRONMENTAL PROTECTION AGENCY

During the last 4 years we have attempted to acquaint ourselves with the EPA and their rules and regulations that govern the use of pesticides. We have relayed the concern of our beekeepers over the country about our bee losses. As a whole we have found the personnel to be cooperative. They have patiently explained their role in the scheme of regulating pesticide use.

To date the FIFRA and the regulations that have been promulgated by EPA has given us little relief. And the future looks worse. For instance, time release pesticides presents problems that are far greater than any our industry has faced to date. The Pennwalt Corporation of Pennsylvania discovered that they could put a highly toxic chemical insecticide, methyl parathion, in a nylon capsule and make it much safer for man to handle. The product, Penncap-M, is effective against a number of crop pests. However, under certain conditions it retains its toxicity in the environment and will kill beneficial insects, such as honey bees, over a long period of time.

When it settles on flowers, Penncap-M is collected by the Honey bees, returned to hive and stored in pollen. In one instance it remained stored in the combs and killed bees 19 months later.

The EPA and the Pennwalt Corporation remind us that the restrictive wording on the label protects the bees. If the label requirements were strictly enforced, we will agree that our problem would be less; but we have not learned of any incident where strict enforcement has been practiced. We are told that the states are responsible for the enforcement, but we have also been told that strict enforcement is not possible. We feel that the wording on the labels is worthless as far as saving bees is concerned.

CURRENT PROGRAMS THAT ARE HELPFUL

The Integrated Pest Management Program has helped us microscopically, but this has not caught on. In future years this may give us some real relief, but will be too late for a number of us.

The Beekeepers Indemnity Payment Program pays for about 25% of losses, but this program has not been included in the 1981 budget. And at the moment this leaves us very much at the mercy of fate.

RECOMMENDATIONS

We have some recommendations that we feel will partially solve our problem with pesticide use. Please consider the following ---

1. Place heavier stress on the implementation of the Integrated Pest Management Program. Perhaps it would be helpful if the word "pest" was deleted and the word "insect" be used in its stead. Under this name the program would cover the friendly insects.
2. The Department of Agriculture and the Environmental Protection Agency should conduct more research on ways and means to lessen bee losses. Most of the research on this subject that has been conducted to date has not netted much about ways to save bees. In 1977 EPA funded an approximately \$5,000 study at Cornell University under the direction of Dr. Roger Morse that showed feeding non-toxic oils to honey bees 12 to 24 hours before a pesticide application would increase their ability to detoxify insecticides. Perhaps this study should be continued. It might result in finding the proper "rollaids" that could be used in the regular bee feed.
3. There is a great need for an Extension Apiarist at the Washington level to disseminate information about the importance of honey bee pollination to the agricultural economy. Many agricultural books tell the grower in detail how to prepare the seed bed, plant, fertilize, cultivate, irrigate, prune or thin the crop, control harmful insects, diseases, or other pests; and, therefore, bring the crop into the highest stages of flowering. Then the advice skips to the harvest stage. Usually little or nothing is said about the need for transfer of pollen from the male parts of the flower to the female parts -- essential in seed or fruit production of many crops. With the material available about honey bee pollination, an Extension Apiarist could fill this void. He could serve as consultant to the other agencies of government that make the rules and regulations that affect our industry. For example EPA could use this expertise when considering the registration of new pesticides.
4. Ban the use of time release pesticides.
5. Conduct a national study to determine extent of bee losses.

We will certainly appreciate it if the Committee will give serious consideration to the several points I have covered in this statement.

Respectfully Submitted
 Glenn Gibson, Executive Secretary
 The American Honey Producers Association
 P.O. Box 368
 Minco, Oklahoma 73059
 Phone -- 405-352-4126
 April 15, 1980

EXTENSION OF FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

THURSDAY, MAY 1, 1980

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT INVESTIGATIONS,
OVERSIGHT, AND RESEARCH OF THE
COMMITTEE ON AGRICULTURE,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:04 a.m., in room 1302, Longworth House Office Building, Hon. E de La Garza (chairman of the subcommittee) presiding.

Present: Representatives Brown, Fithian, English, Wampler, and Grassley.

Staff present: Robert M. Bor, chief counsel; Glenda L. Temple and Peggy L. Pecore, clerks; Gary Norton, Bert Pena, Gerald R. Jorgensen, and Tom E. Adams.

Mr. DE LA GARZA. The subcommittee will be in order.

This morning we have two witnesses and the Administrator of the Environmental Protection Agency. They were unable to appear at the previous hearing.

The Administrator has just informed me that he has a very important meeting to attend later this morning that he had not anticipated. Therefore, with the permission of the first two scheduled witnesses on the list, I am going to ask the Administrator of the Environmental Protection Agency to appear first this morning so that we may accommodate him for his meeting later.

Mr. Administrator, we welcome you and we appreciate your being here.

If you would give us an overview of your administrative and policy issues as they relate to FIFRA we would appreciate it.

I understand you will leave your associates behind who will give us a more detailed report on your activities.

I might inform you that these hearings, for obvious reasons, have turned into a combination oversight and legislative hearing so that we may be going from one to the other at any point. If you will take that into consideration in your report, it will be appreciated.

STATEMENT OF DOUGLAS M. COSTLE, ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY STEVEN JELLINEK, ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES; RICHARD WILSON, DEPUTY ASSISTANT ADMINISTRATOR, GENERAL ENFORCEMENT; AND ED JOHNSON, DEPUTY ASSISTANT ADMINISTRATOR, PESTICIDE PROGRAMS

Mr. COSTLE. Thank you very much, Mr. Chairman. I very much appreciate your consideration and I apologize to the other two gentlemen. This came up somewhat at the last moment.

I will try to keep my remarks brief. Mr. Jellinek is also here with me. He is the Assistant Administrator in charge of this program. Mr. Ed Johnson is the day-to-day director and Dick Wilson is from our enforcement division.

I am pleased to be here to discuss with you EPA's progress in administering its pesticide regulatory authorities. My prepared remarks will emphasize our implementation of the 1980 amendments to the FIFRA, which were intended to cut through administrative knots which threatened to bring our regulatory program to a standstill.

We feel that we have made substantial improvements in pesticide regulation and that the benefits of the improvements have transformed our program.

I might say here that this progress is in no small way attributable to the time and energy given the problem of pesticide regulation by this subcommittee and the full committee and to the close working relationship developed between us over the last few years.

In 1977 I made my first appearance as Administrator of the Environmental Protection Agency in a congressional hearing before this subcommittee. I came to you with the serious problems then confronting EPA's administration of the FIFRA. I asked for, and in the main you gave us, a range of new authorities to deal with the pesticide registration logjam, trade secret protection, the compensation question, and use enforcement, among other things.

It took 1½ years of thorough, rigorous deliberation and the results did not make any party to the legislative process entirely happy, but we got what I think is a workable law out of it.

The core of the problem then was, first, the paralysis of our registration program caused by litigation over industry's trade secrecy and data licensing claims; and, second, the related inability of the registration program to function efficiently and fairly under the FIFRA as then written.

The 1978 act contained a number of amendments dealing with those problems, including the authority to give conditional registration to certain pesticide products close to the full registration and to set standards for all products containing the same active ingredient.

We predicted, when the 1978 amendments were enacted, that we could get pesticide registration rolling again and we have. Our conditional registration regulations were promulgated in record time, on May 11, 1979.

We now have a 75-percent approval rate as opposed to nearly zero before the 1978 amendments. Of the over 10,000 registration actions we have taken since the amendments, 600 are conditional registra-

tions involving old chemicals and 21 are conditional or full registrations of new active ingredients.

However, I would be remiss if I did not bring to the committee's attention obstacles which have been encountered in our efforts to implement registration reforms. While the obstacles have not yet created the serious problems for applicants, particularly formulators, which were encountered under the old law, the potential for major disruption—including a drastic curtailment of the conditional registration program which industry generally praises—looms on the horizon.

As has been the case in the past, the basis for the threat is found in continuing industry contention over the statute's treatment of pesticide effects data. I am sure that this committee will have no difficulty recalling that litigation about data disclosure under section 10 and data licensing under section 3(c)(1)(D) of FIFRA was a major cause of the paralysis of the registration program in 1977.

In attempting to get the program moving again, the Congress, EPA, the pesticide manufacturing industry, farm representatives, and other affected groups devoted an extraordinary amount of attention to these provisions in the legislative proceedings which produced the 1978 amendments. As I indicated earlier none of the participants in this debate got all that it wanted.

However, I believe that the Congress struck a sound and workable compromise, and I thought that everyone—including the industry—was prepared to accept Congress' compromise, lay down their weapons, and work with the Agency to make the act work.

Unfortunately, this has not happened. Instead, the pesticide manufacturers have launched a new and even more vigorous attack in the courts on section 10 and section 3(c)(1)(D).

While we expect ultimately to prevail against the challenges, they have caused serious disruptions in our attempt to implement fully some of the provisions of the 1978 amendments, particularly the registration standards program.

But, I do not want to sound pessimistic this morning, Mr. Chairman. I believe the program's vital signs are strong. Given the litigation problem, we are making good progress on the implementation of registration standards.

Last December 26 we published an "Advance Notice of Proposed Rule Making" for public comment which described the basic features of the standards system. We are presently making adjustments to the system in response to comments received and we have recently made available a prototype standard using the chemical metolachlor.

In addition, we are about to publish in the Federal Register a list of 55 pilot chemicals for which we need bibliographic information and a notice describing our data call-in program. These actions should provide us with the depth of data necessary to produce registration standards. The next step—in late spring—is to publish the list of all 500 to 600 basic chemicals in the sequence in which we plan to develop the standards.

Once all this is in place we will have statements of all approvable uses and formulations of all products containing the same active ingredient. We will be able to decide on a registration application simply by determining the relation of the proposed pesticide product to the

standard for that chemical, the data on which will already be in place and available.

The benefits of swift approval to producers and users are obvious, but just as important is that public confidence in pesticide regulation will be enhanced. With the program's recent history in mind—where three independent evaluations found much of the health data relied on to make regulatory decisions to be of dubious validity—the systematic review and evaluation of data which are accomplished in building the standard is vital to creating confidence.

A strong, reliable Federal program is the best response to public concerns which have prompted State and local governments to consider adopting their own restrictive pesticide controls. You have heard pesticide manufacturers express fears about this trend. We would point out that their support of a strong Federal program would be a wiser course than attempting to get the courts to enjoin State programs clearly authorized by the Congress in 1972.

Our rebuttable presumption against registration program for review of existing registrations concluded 12 major actions since September 30, 1978, which is exceptional progress given the depth and thoroughness of the review. These actions have helped dispel the fear that RPAR was just a longer way of saying ban. Of the pesticides scrutinized, about half were retained with added precautions and others had as many uses added as they lost. Three are proposed for cancellation.

Under the FIFRA provisions governing the use classification of pesticides by regulation we have classified 36 active ingredients involving about 2,500 products for restricted use and have proposed restrictions on the use of another 21 active ingredients.

We have managed to keep up with a surfeit of emergency exemption requests under section 18, maintaining an average 7-week turnaround time. During 1979 we processed almost 2,000 special local needs registrations and have assisted the States in complying with the 1978 amendments to this program. We have given priority to meeting minor-use tolerance and registration needs, and we have nearly completed implementation of State enforcement and experimental use authority added by the 1978 amendments.

All in all, Mr. Chairman, while we have a long way to go, I am quite encouraged. Our job can be viewed as maintaining a dynamic tension between the needs of farmers and consumers on one hand and the environment and public health on the other. The signs are that we are succeeding. The pesticide industry is strong and growing. Agriculture is still able to hold the pest world at bay, and through regulation and industry refinements we are insuring that the benefits of pesticides outweigh the risks inherent in their use.

The program is moving forward again, after the nadir of 1975-77 which was brought on by progressive paralysis from litigation over the sweeping amendment of FIFRA in 1972. The 1978 amendments mean that EPA can once again assure that agriculture has the tools to combat pests while diminishing to an acceptable level the adverse environmental and health effects of pesticides. We are anxious to continue the productive working relationship we have established with you.

Mr. Chairman, that concludes my prepared statement. I would be pleased to answer any questions you may have.

Mr. DE LA GARZA. Thank you very much, Mr. Costle.

Are there any questions? Mr. Fithian?

Mr. FITHIAN. Thank you.

I am sorry that I was not here at the beginning of your statement, Mr. Administrator. You were competing with the Ambassador of Japan's reception momentarily.

I have several questions. I see that you have your top brass with you this morning, so it is really immaterial whether you or they respond.

The industry is now expressing rather considerable concern for what looks to be a development in which various States will set their own standards, requirements, et cetera, which differ from the national standards that are promulgated by EPA. It goes without saying that for a nationally marketed product, this situation has the potential for causing some rather considerable problems.

I wonder if you could comment on the direction in which that is going and on any recommendations that you have or the Agency has.

Mr. COSTLE. We would be happy to, sir. In some respects I am sympathetic to the concern that is expressed by the industry that they may get a variety of different approaches in different States. On the other hand, in a sense I think they are tending to bring some of that problem on themselves.

As you know, I am really quite angry about what I consider to be a breach of what I thought was a commitment made both to the Congress and to us over the issue of litigating the 1978 amendments. I think that is causing us more and more concern. It is causing doubts in other people's minds about the efficacy of the program.

I think there is a certain amount of irony in the situation. Here is an industry that prefers to be regulated by the Federal Government. Of course, in 1972 there was a lot of debate about the respective roles of the State and Federal governments. Now that the States seem to be moving forward, to the extent that that is perceived by the industry not to be in their self-interest, they are suddenly becoming newfound federalists.

I would ask Steve and Ed to add to that if they care to.

Mr. JELLINEK. Thanks, Doug.

Mr. Fithian, we are aware in particular of the industry's concern about the State of California's pesticide registration program and we have also talked with the State people about it. There are several aspects of that program about which there is contention and controversy.

I think the question you asked directed itself specifically to whether States ought to have the ability to mount a pesticide registration regulatory program. I think on that question we clearly support the California position and what we think is the position of FIFRA, that there is a need for States to act in situations that are unique and special to State concerns and to the local agricultural situation, geographic or climatic situations, or pest situations, and that as long as State actions do not counter the national objectives and the national standards set by EPA under FIFRA, that is a thoroughly appropriate role for States to play.

Mr. FITHIAN. Mr. Chairman, I will ask one more question and, hopefully, after others have had their turn, I can get back to two other questions I have.

The most important complaint that we have had in previous testimony—and it was discussed by practically every witness. I will read for you what I think might be the most succinct statement of the problem, in the testimony of Dr. Jack Early of NACA. It deals with the cite-all regulations:

NACA is concerned that the legality of EPA's cite-all regulations, insofar as they require an applicant for registration to pay duplicate compensation for test data, even though the applicant has already paid for and submitted to the EPA all of the data required for registration, * * *

skipping on down,

NACA believes that under paragraph 3(c) (1) (D) of FIFRA, if an applicant submits data of its own which fully satisfies EPA data requirements, there is no basis for the EPA to compel the applicant to rely on any other company's data to support the applicant's registration or to require the applicant to pay compensation for use of any additional data.

Nevertheless, the cite-all regulations require an applicant for registration to pay compensation for all other data in EPA files which pertain to the registered product, even if the applicant has submitted its own data.

and then they make a citation.

I am sure this cite-all problem has been discussed at the Agency, but if you would like to have this particular statement, since it was a little long in the formulation of my question, I would be glad to hand it over to you.

I wonder if you could comment on the problem and upon what EPA is doing, or can do, or plans to do with that particular problem.

Mr. COSTLE. I would be happy to comment on that, Mr. Fithian, and then ask Steve Jellinek to elaborate.

Since 1977 it has been our publicly announced intention to reregister by first examining all scientifically relevant data and by preparing standards. We have considered that vital to the integrity of the program that the Agency be free to consider all scientifically relevant data.

I think industry concedes the logic of that position. As you may recall, during the legislative process resulting in the 1978 amendments we assumed data submitters would insist on compensation for any post-1969 data on which an EPA decision to unconditionally register or register a product relied in any degree. We had previously been sued by data submitters claiming insufficient protection. Subsequent litigation had, as you recall, catastrophic effects on the program and the new litigation I spoke of earlier has similar potential to undermine the basic registration program.

EPA has taken a cite-all approach not only for unconditional registration and reregistration but also for conditional registration of technical products because 3(c) (7) of FIFRA specifically requires submission of "such data as would be required to obtain registration of a similar pesticide under section 3(c) (5)."

Registrants of end-use products made from others' registered technicals have the option of submitting their own data. That is what we refer to as the alternate method of data support. Registrants of end-use products made from their own technicals must cite all for data on the technicals but may submit their own data for the end use. That is a

combined method of data support. Registrants of manufacturing-use products, that is technical-grade material, must cite all permanent data. There are very few duplicate studies on technical grades, but each one is valuable in assessing effects they measure, either cancer, birth defects, or others.

Industry, as you know, has begun new litigation concerning cite-all but, frankly, has advanced no practical alternative to it. As Steve Jellinek will discuss in detail in his statement, their proposed solutions, in our judgment, amount to a choice between enormously wasteful application-by-application approaches to registration or the illegal consider-but-do-not-compensate approach.

At this point I would like to ask Steve to elaborate.

Mr. JELLINEK. I think that sums it up pretty well, Doug. I really do not have much else to say, except that we continue to remain somewhat mystified by the industry's position on this. We believe that the reason why we have been able to implement the conditional registration program so quickly and to make it operate so successfully is because we have stipulated, in essence, that we are not going to review data. We are going to assume that decisions made on existing pesticides were made correctly, even though there are data gaps and even though we have not reviewed some of that data recently.

If we had to rereview data in every circumstance, the system would break down. We think that the cite-all provision simply reflects the fact that EPA has considered that data and cannot divorce its decision from its prior consideration of the data. Thus, under the terms of the act, we are required to request that industry offer compensation.

I do not think I ought to go into any more detail. There is more detail in my testimony and perhaps we can get to it further later on.

Mr. COSTLE. We would also be happy to expand for the record at any time on that subject.

Mr. FITHIAN. Thank you, Mr. Chairman.

Mr. DE LA GARZA. Mr. English?

Mr. ENGLISH. Thank you, Mr. Chairman.

Mr. Costle, this year western Oklahoma has over 1 million acres of rangeland that are threatened by a grasshopper plague that will devastate the food production and bring financial collapse on an already hard-pressed farmer and rancher. It is my understanding that in all Western States an estimated 32 million acres of rangeland are in danger.

I simply want to know what assistance EPA is giving the Department of Agriculture in assisting them to attempt to deal with this immediate problem.

Mr. COSTLE. I would be happy to elaborate on that, Mr. English. In 1978 and again in 1979, because of serious infestations in a number of Western States, we developed basically a 3-fold strategy to try to assist farmers in effectively controlling grasshoppers. This strategy included, first, the continued rangeland treatment with Carbaryl and Malathion; second, the treatment of field margins with Endorin and Toxophene baits; and, third, treatment of crops with currently registered products or those suitable for emergencies or States' special local needs registration.

This year we have just recently provided the Western States with updated information on those pesticides suitable for special local

needs registrations. These are: Carbofuran, Chlorpyrifos, Endorin, Acephate, and Dimethoate.

This year the Office of Pesticides has been working with APHIS, the USDA, on its EIS for the grasshopper control program. We have made a number of recommendations. It is my understanding that we have had a series of meetings recently with them wherein there has been compromise on both sides and that we are pretty close to an agreement.

I have asked Steve Jellinek to work directly on this with Assistant Secretary Smith to try to get it resolved and resolved in a timely way.

I would invite Steve to add any comments that he would like to add.

Mr. JELLINEK. I do not have anything to add. I think that covers it. If you have additional questions, I would be glad to go into—

Mr. ENGLISH. Is it not true that in February of this year the EPA recommended aerial application standards for the use of pesticides which EPA registers for this purpose that would severely cripple if not completely prevent the success of any aerial spraying program on this problem?

Mr. JELLINEK. Let me try to give you some background on this, Mr. English. Last year, in conducting their spray program, in one State—and I am not sure what State it was—one of the applicators basically got busted for allowing spray drift to get into a small pond. There is some thought that perhaps that pond might have dried up in perhaps 3 or 4 weeks after the spraying so it was an intermittent pond.

APHIS came to us early in the development of their program after that and asked us to help them informally to develop environmental protection aspects of the program so that they could avoid that kind of problem.

Let me give you an example of how that kind of problem arises. One of the pesticides used in that program has a label that says: "Toxic to fish. Keep out of lakes, streams, ponds." Whoever the enforcement officer was that busted that applicator was entirely within the label.

We know that our labels have to be updated because they were written at a time when they were not enforcement tools and in many cases they have not been updated to reflect that.

We work with APHIS—

Mr. ENGLISH. Is it not true that in the recommendations that you came out with you said, basically, that there would have to be a 1-mile wide buffer zone around so-called sensitive areas, such as highways, school yards, churches—

Mr. COSTLE. Mr. English, since APHIS has assured us that they will not overspray inhabited areas, we are not recommending now that there be buffer zones. We did recommend buffer zones for certain water resources in other areas, but based on APHIS's assurances to us we are not recommending buffer zones around inhabited areas.

Based on a recent supplement of APHIS' environmental statement, we are now suggesting some significantly lessened precautions over what we recommended to them in February, so when I said—

Mr. ENGLISH. You are saying that the February recommendations no longer apply, that you—

Mr. COSTLE. That is correct. We are in the process, as I understand it, of sitting down with APHIS and trying to work this thing out and I think we are reasonably close now.

Mr. ENGLISH. Would you agree that as far as any alternate ground application or any hand baiting that would meet your guidelines is concerned that from the standpoint of this particular problem that would not be practical, because this problem is on us and has to be dealt with within the next month or two?

Mr. COSTLE. I am going to defer to Mr. Jellinek.

Mr. JELLINEK. We think that the problem has to be dealt with and we want to deal with it in a responsible way. We have to work together with APHIS to do that.

Mr. ENGLISH. What I am saying is that the reality of the matter is that it will have to be dealt with primarily through aerial application.

Mr. JELLINEK. That is correct.

Mr. ENGLISH. There is no other way of dealing with it.

Mr. JELLINEK. That is correct.

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

Mr. DE LA GARZA. Mr. Grassley?

Mr. GRASSLEY. Mr. Costle, in your statement you referred to 3(c) (1) (D). You said, "Instead, as EPA legal counsel has briefed me, the pesticide manufacturers have launched a new and more vigorous attack in the courts in section 10 and section 3(c) (1) (D)." Is this what we refer to as the cite-all provisions?

Mr. COSTLE. That is correct.

Mr. GRASSLEY. All right. Would you elaborate on why you apparently feel the law and the regulations should not be challenged.

Mr. COSTLE. I would be happy to. Steve, do you want to pick up?

Mr. JELLINEK. As I said before, we think that the issue is simply this: We have studies in our files that we have reviewed and taken a position on. They are part of the institutional knowledge of the agency. We cannot use that knowledge to grant a conditional registration on the one hand without reviewing that data and on the other hand say that the companies that gave us that data or knowledge do not have a right to compensation under 3(c) (1) (D). It is just logically inconsistent.

The industry position is that if they provide all the data that our guidelines call for, then they should not have to rely on other data in our files. That has a certain surface logical appeal but in fact we have relied on these data in making our decision. The studies that we are talking about are not simple acute toxicity studies. They are often chronic studies or subchronic studies and they often turn out slightly different and involve scientific interpretation. Our scientists, in interpreting these types of studies, do take into account slight differences in individual studies and try to come to a responsible scientific conclusion.

Prior to the 1978 amendments one of the courts dealing with this issue recognized that EPA cannot have a selective institutional memory on these facts. Our implementation of the 1978 amendments and our interpretation of the 1978 amendments simply reflect that fact.

Mr. GRASSLEY. Does EPA plan on modifying its regulations relative to cite-all or do you believe that any congressional action would be necessary? Would you recommend any congressional action?

Mr. JELLINEK. We would not recommend any congressional action. We do not intend to modify it at this time.

We have had preliminary discussions with NACA's representative to see if there is some way out of this mess on which we could all agree

and that would result in everybody getting his way: EPA not being subject to challenge for failure to rely on certain data that are in its files and NACA members being able to circumscribe the amount of data for which they would be required to compensate.

This is not an environmental or health protection issue, as you know. It is an issue of commerce and economics and property rights. We hope that we and the industry will be able to come up with some solution. If not, it may eventually take some congressional action.

Mr. GRASSLEY. I made a statement on November 26, 1979, wherein I outlined my concerns about the cite-all controversy. I would like to know if you are aware of my statement?

Mr. JELLINEK. I am aware of it, Mr. Grassley, but have not read it recently.

Mr. GRASSLEY. I guess I would then ask you to make a response in writing to our committee taking into consideration my concerns. I hope that the concerns of Members of Congress about the enforcement of legislation would be given some weight by executive agencies.

I would like to have your response to some of the points I made, specifically, with respect to costs.

Mr. COSTLE. We would be pleased to have an opportunity to respond point by point to your letter and we will do so.

Mr. GRASSLEY. Also, it has been alleged that EPA has been involved in what is commonly referred to as funding intervener groups. Could you tell me if this is true; that you are involved with funding intervener groups?

Mr. COSTLE. Not in these programs.

Mr. JELLINEK. Not in the pesticide programs.

Mr. COSTLE. Under the Toxic Substances Control Act there is, as I recall, explicit provision for intervener funding.

Mr. GRASSLEY. Are these statutory provisions? That was my next question.

Mr. COSTLE. That is correct. If you would like, we would be happy to supply for the record a complete statement as to just what the Agency is doing in that area.

Mr. GRASSLEY. All right. I would also like to have you tell me who is getting the money.

Mr. COSTLE. I would be happy to do that.

Mr. GRASSLEY. Thank you.

[The responses from EPA appear on p. 102.]

Mr. DE LA GARZA. Thank you very much, Mr. Costle.

We have a problem in that Mr. Wampler, a ranking member, is addressing his alma mater, the Virginia Polytechnic Institute, this morning. He was very interested in having some dialog with Mr. Jellinek. I wonder if you could be available this afternoon?

We have the Secretary of Agriculture too, which, I assume, might take both Mr. Wampler and me away from this subcommittee for about an hour. Therefore, we would probably be able to be here by 3. Would you be available this afternoon so we might continue your dialog and afford Mr. Wampler the opportunity to be here?

Mr. JELLINEK. Yes, Mr. Chairman.

Mr. DE LA GARZA. Thank you very much. We appreciate your cooperation.

Mr. Fithian has one further question.

Mr. FITHIAN. Thank you.

I want to stay with this cite-all thing for just one more round of discussion. Section 3(c)(1)(D) provides for either registration by filing test data supporting the claims, as I understand the way we wrote it, or for filing a citation to data previously submitted by others.

Some allege that the EPA then, in requiring the latter which is essentially the cite-all process, exceeds the statutory authority by requiring the applicant who has submitted complete data on his own—enough data to actually document and demonstrate that the chemical could be used—to pay for other test data that is not required or that he does not require, merely because it happens to be in the EPA file.

I would like to have your comment on that.

Mr. COSTLE. We are getting into some of the more arcane aspects of legal interpretation of those phrases.

I could provide a legal opinion on how we have interpreted that and why in detail. However, we do interpret the whole section, beyond the either/or to mean that it is the Administrator's call as to the either/or, not the manufacturer's call. I think that may be where the difference is.

Mr. FITHIAN. You do not have to answer this if you do not want to since I know you are tangled up legally on it. As a layman, it seems to me the reason you have gone to this "spreading your skirts" device is to protect your legal flank against somebody who comes in and says, "Wait a minute. You know, I have some data in the files down there, too, and I did not get paid for it."

Mr. COSTLE. That is not an unreasonable point of view. That is what we lost a case on prior to the 1978 amendments and that is what tied up registration for so many products for so many years.

It is a legal question plus a policy question. That is the legal side. The policy side is that in fact we have reviewed these data. We have based decisions on them. We cannot ignore that.

Mr. FITHIAN. Could we help get this out of the jungle by altering the statute?

Mr. COSTLE. As I said to Mr. Grassley earlier, if we cannot work out some kind of arrangement or interpretation with the industry on this, we may very well be coming to you to ask for a statutory clarification on it.

Mr. FITHIAN. Last, I just have a comment for the Administrator. We appreciate the cooperation that you and all of your staff—I have worked for many hours with Ed Johnson and your other staff, and over the years I have found that to be rather helpful and found them very cooperative.

However, there is developing, Mr. Chairman, a process which is beginning to really bother me personally as just one member of the authorizing subcommittee. This is a very technical subject and if you are going to tool up to deal with it in the authorizing committee, it takes a very considerable amount of staff time and personal time of somebody who is on half a dozen other subcommittees. There are a lot of other things that you could be working on.

Then we seem to have the process being essentially subverted. I am not sure but what we all contribute to this. You really tend not to have to worry about us if you can bypass us and go to the Appropriations Committee.

I know that and you know that if we are going to level with each other. There are times when those of us who have put in so much time on the technical side, working with your people, working with industry, and so forth, seem to just have the enormous temptation to just throw up our hands and say what is the use, if you bypass this whole process of rather detailed analysis of what has to be done, what is being done, and the oversight responsibilities, and the legislative responsibilities, and so on.

If you simply bypass us and go to the Appropriations Committee—Mr. de la Garza has been rather cooperative and has not really lodged the enormous kind of protest that I think we could as the authorizing committee. We could just say, “look, if you do not work it out and we do not work it out, there is going to be no appropriation.”

In fact, the philosophy of the Agriculture Committee, when we went to the short appropriations process, was primarily a response—you should know this because it preceded your coming here—to the enormous pressure that those of us were under who represent agricultural America.

As you well know, or Dr. Johnson certainly knows, the movement out in the cornfields was: “Why don’t you do away with EPA, period.” Some of us took an awful lot of heat in saying, “No, that would not be the right policy.” We worked long and hard trying to devise a workable policy.

As one member of the subcommittee, Mr. Chairman, I am getting down toward the end of the road of patience on this. We are going to exercise authority over this program. We are going to review the program and we are going to act on the review. You are going to have to live with us and we are going to have to live with you, or, as one member, I am going to stop putting in the hundreds of hours that I put in on FIFRA. I just want to tell you that.

I understand your problem. If we do not get through because of differences of opinion in the full committee, and so on, and you have to have funding, I understand the reason for the shortcut and the end run that you are doing.

However, I would not be very honest with you if I did not say that as one person who has worked for 4 years on FIFRA, sometimes on a night and day basis with the States, with your people, with industry, with farm groups, I am not going to go down this road very many more times and very much further.

Either you are going to come to terms with the problems we wrestle with in agricultural America or there is going to be some day of reckoning. As far as Floyd Fithian is concerned that is not very far off.

I did not really mean to editorialize this morning, Mr. Chairman, but it does get a little bit frustrating.

Mr. COSTLE. Mr. Chairman, if I have an opportunity to respond.

Mr. DE LA GARZA. Yes.

Mr. COSTLE. First off, I hope you do not lose interest because, quite frankly, it has been I think enormously constructive for everybody to have you involved to the degree that you have been involved and to have the effort that you and other members of this committee have put in on very tough issues for which there is just no clear right and wrong.

I was not aware of your perception that we were pulling some kind of an end run. Frankly, my understanding of that was that we just got so very bogged down over a couple of things, if you recall, that something had to be done. It was not done with any malicious intent or as part of some sort of calculated strategy to bypass this committee.

My impression of it was—I am being very frank—that was a necessary expedient while we still tried to sort out that very difficult situation last year which eventually did get sorted out.

I agree with you. That is not the preferred way to work, but I am being absolutely honest when I say to you that I hope you do not drop your interest in this. You have been an absolutely critical person to rationally sort out some of these issues. They are tough issues. We have appreciated the opportunity to work closely with you.

Mr. FITHIAN. I understand the exigency when you get down toward the end of the fiscal year.

Mr. COSTLE. We had the specter of an Agency that shut its doors today as a result, you and I both know, of—

Mr. FITHIAN. All right. Take the Federal Trade Commission, for example, and take you own Agency, for example. The enormous controversy surrounding that and not too much less surrounding this ultimately gets resolved in the cauldron, the pressure cooker atmosphere, and the urgency or emergency which arises.

We have and you have—in the environmental movement and with those who concern themselves about adequate pesticide control and registration in the Congress—people who can get very exercised if push comes to shove. However, if you never quite get to where push comes to shove then you do not resolve the key problems. You can always Band-Aid over it if you get the appropriations. It does not have to be faced either by you or us.

That is what is wrong with the process of short-circuiting the system.

Thank you, Mr. Chairman.

Mr. COSTLE. I understand that. I think that is a valid point.

Mr. DE LA GARZA. Mr. Costle, I hope you don't get into the situation they did. I have not seen one tear shed around these halls for the agency that has to shut down today, because of some of the tactics which they have used.

Also, my dear colleague, Mr. Fithian, I think I reached the decision before you that we will follow the rules—no authorization, no appropriation. We will raise the necessary point of order if it should come to that.

Mr. Brown, do you have any questions or comments? We are in the comment period.

Mr. BROWN. I have no questions.

Mr. DE LA GARZA. Thank you very much, Mr. Costle.

Mr. JELLINEK. Thank you.

Mr. COSTLE. Thank you, Mr. Chairman.

[Responses from EPA to Mr. Grassley follow:]

Attachment 1

Mr. Grassley asked the Agency to provide the Committee with information on the instances in which EPA has provided intervenor funding to outside groups to enable them to participate in regulatory proceedings.

EPA began considering the advisability of compensating selected participants in Agency rulemakings for their costs of participation in 1976. Specifically, on June 11, 1976, the Environmental Defense Fund, joined by Consumers Union and the Center for Auto Safety, filed a petition for rule-making to provide for agency reimbursement of the cost of public participation in EPA decision-making. The petition sought compensation for participation in all types of EPA regulatory proceedings under all EPA statutes.

On January 7, 1977, EPA published in the Federal Register an Advance Notice of Proposed Rulemaking, signed by former Administrator Russell Train, stating that the petition had merit and warranted serious consideration, and asking for public comment on it. (42 FR 1492, January 7, 1977.)

About 400 comments were received. Most of them opposed the proposal, typically arguing that it would be unfair to fund one point of view in EPA regulatory proceedings without funding all points of view. Others argued, in a variation on this point, that such a system could be abused to systematically fund one particular viewpoint in preference to others. In addition, many comments argued that such a scheme would be administratively impractical, or too expensive, or likely to cause undue delay.

In part in reaction to these comments, EPA deferred any general action on the subject of the petition. Instead it established a "pilot program" under section 6 of the Toxic Substances Control Act. This section confers explicit authority on EPA to establish a "public participation" compensation program, and the legislative history makes clear that Congress expected that authority to be used. The notice stated that the question of a more general compensation program would be reevaluated after the pilot program was complete. (42 FR 60911, November 30, 1977.)

The pilot program concerned EPA's rulemaking to implement a statutory ban on the manufacture, processing, distribution, and use of polychlorinated biphenyls (PCB's). Two applications for compensation were received. One failed to meet the requirements of the interim program. The other, from a New York based group, the Center for Occupational Hazards, Inc., offered to provide information on the use of PCB's in microscope optical systems. EPA had not known that PCB's were used for this purpose, and it involved an obvious potential for human exposure. EPA spent \$1522 (out of \$10,000 available) to fund this group's participation and it provided useful factual information. EPA's administrative costs were negligible.

There have been no other instances in which EPA has provided intervenor funding to outside participants in the Agency's regulatory process. We are, however, planning to extend this public participation compensation program on a pilot basis to other rulemaking activities. Rules issued under the FIFRA, however, will not be eligible for funding under this extended pilot program.

Attachment 2

Mr. Grassley has asked the Agency to respond for the record to his remarks in the November 26, 1979, Congressional Record concerning "cite-all." In these remarks Mr. Grassley suggests that the FIFRA establishes a "two-track system" for applicants to meet their obligations to provide sufficient data in support of product registration. It is his understanding that a registrant may tell the Agency which data he wants the Agency to consider in support of his product's registration - these data may either be his own or, alternatively, citations to data in public literature or previously submitted to the Administrator.

This is essentially the same position which NACA presented in its testimony during the April 15, 1980, FIFRA reauthorization hearing. Mr. Steven D. Jellinek, Assistant Administrator for Pesticides and Toxic Substances responded to that position at length in his May 1, 1980, testimony:

Our reasons [for cite all] ... are detailed in a 10-page letter to Senator Stewart, Chairman de la Garza's counterpart subcommittee chairman, dated February 11, 1980, which was made available some time ago to the Committee staff. A copy of that letter is attached to my prepared testimony, for the convenience of the subcommittee members.

As we indicate in that letter, in 1977-78 the Agency made clear to Congress our intent to review all relevant data in preparing the registration standards which we will use as the principal basis for unconditional registrations under §3(c)(5) in the future. We also note that FIFRA §3(c)(7) expressly requires conditional registration applicants to rely, for data compensation purposes, on the same data that would be required for a §3(c)(5) registration.

NACA has indicated they will propose a system under which (1) an applicant would tell us which data he wanted us to consider "in support of" his application, and (2) we could look at whatever other data we felt necessary "so long as [the other data] are not used [by EPA] to affirmatively support" the application. This proposal is the same one that was advanced by NACA to us last summer. At that time, we told them that their approach had two fundamental flaws that precluded its adoption:

-----The NACA approach would not work in cases where we do consider all relevant data before deciding a product could be registered (i.e., when we develop a registration standard), because, as the courts have noted, our scientists can't pretend to "forget" part of the data base for the convenience of applicants, and also because the whole reason for using a generic approach to registration is to get away from

the same inefficient, duplicative review of portions of the data base that the NACA approach would require.

-----The NACA approach would not work in cases where we do not consider all relevant data before deciding a product can be registered [i.e., all the conditional registrations now being issued under §3(c)(7)(A) and (B)] for the simple reason that under the NACA approach, EPA would have to review all the data the applicant puts before us, on an ad hoc basis, for the sole purpose of deciding whether he had submitted enough data to avoid a claim by some other data owner that the latter's rights had been violated. Conditional registration of me-too products, and of new uses for old products, expressly contemplates that we will not review data on existing uses. The idea is that we can use our resources better in the development of registration standards and other tasks, and should not hold up marketing of me-too products or new uses pending ad hoc reviews of data on existing uses.

A resolution of the cite-all issues in a fashion that would allow conditional registrations to be issued as Congress intended, and would allow us to adopt the efficient registration-standard approach to unconditional registration that we believe Congress endorsed in 1978, is outlined in the letter to Senator Stewart at page 8. We really do not have a preference on the question of whether applicants compensate data submitters for all, some, or none of the relevant data. So long as EPA is not precluded from attaining an efficient program for evaluating pesticides and issuing registrations as Congress intends, and so long as we can avoid yet another round of litigation commenced by individual firms, whatever the industry as a whole can agree upon about the extent of data compensation will be acceptable to us.

In his November remarks Mr. Grassley also suggested that if the Agency did not follow this two-track system, that the Committee on Agriculture should explore the cite-all issues during this year's authorization hearings.

As it turned out, however, the Committee was unable to develop any legislative solutions to the cite-all issue this year because of time constraints, but did adopt report language making clear that the Administrator determines what data must be submitted or cited by applicants and that the Administrator determines what data are relevant to registration decisions. The Committee has also directed the Agency to "explore all available options for administrative relief to this problem" which we will do during this next year. We will also be ready to work with the Committee on possible legislative solutions when time permits.

MR. DE LA GARZA. We will have the first scheduled witness that we had to pass over in order to accommodate Mr. Costle. That is Mr. Victor Winik of the International Sanitary Supply Association.

We will hear from you at this time, sir. Your full statement will appear in the record after you summarize or quote from it. That would be perfectly agreeable to us.

STATEMENT OF VICTOR WINIK, CHAIRMAN, REGULATORY ADVISORY COMMITTEE, INTERNATIONAL SANITARY SUPPLY ASSOCIATION

MR. WINIK. Thank you, sir.

Good morning. My name is Victor Winik and I am chairman of the Regulatory Advisory Committee, which is part of the International Sanitary Supply Association. Our headquarters are located in Chicago and we have approximately 2,600 or 2,700 members.

The responsibility of our industry is to attend to the sanitation and maintenance industry of the United States. We maintain and provide materials to maintain sanitation for hospitals, buildings, schools, and all other such places.

I came before this committee approximately 1 year ago and discussed some of the problems that our industry was facing. Today we face many of the same problems that we faced approximately 1 year ago.

The major problem that we are still facing is this condition of cite-all. It was our understanding that the cite-all situation, as it was originally referred to, would only have compensation given to the original data submitter. We have been put in a position as small businessmen of having to write as many as 200, 300, and 500 letters to many many people trying to seek out to whom it is that we have to give compensation.

Some of the replies that some people in our industry have received are requests for compensation far in excess of the net worth of the company that existed. I, myself, have had requests for compensation in the range of \$200,000 to \$300,000.

We feel that if we were told, or if it were so, that the Federal Register could give notification of the registrant's request for a registration and that the responsibility be given back to the original data supplier to seek out whomever it is that is trying to seek out a registration, this would greatly help our position today.

We also have problems with proposed guidelines. We are put in a position wherein we try to abide by the guidelines as set forth by the Environmental Protection Agency and we find that as we begin to approach meeting the guidelines new guidelines are put into effect. This becomes a major problem for us, but it is a problem that we could possibly deal with if we knew we were only dealing with guidelines that were made a part of the law. However, when we have to begin to deal with a draft form of a guideline, we begin to run into other problems.

The major problem that we face today, and it is something that we feel can be very, very easily cleared up, is supplemental registrations. If the supplemental registrations were put in a form such that when

it was originally submitted by the manufacturer in his process of getting a supplemental registration for a distributor, his material has already been approved and he already has a registration number for the material, we feel that it would be almost unnecessary to have to wait 6 or 8 weeks, or as many as 10 or 12 weeks, to have the distributor given a supplemental registration.

During this period of time what we have done is we have limited competition within a given area. These people do not have the particular material to sell. Their sales are held down. We feel we could cure this by simply writing a letter to the Environmental Protection Agency listing the name of the manufacturer, the name of the applicant for the supplemental registration, and at that point going on to supply the person with the original material that was already approved. Thank you.

Mr. DE LA GARZA. Thank you very much.

Does any one have any questions? If not, thank you very much. We appreciate your presence and without objection, your entire statement will be included in the record at this point.

[The prepared statement of Mr. Winik follows:]

STATEMENT OF VICTOR WINIK, INTERNATIONAL SANITARY SUPPLY ASSOCIATION

My name is Victor Winik. I am Chairman of the Regulatory Advisory Committee of the International Sanitary Supply Association. ISSA is located at 5330 North Elston Avenue, Chicago, Illinois 60630. It has been in existence over 56 years and is composed of more than 2,500 manufacturing and distributing, small business firms engaged in producing and selling cleaning and maintenance products and supplies used in hospitals, schools, food establishments, commercial businesses and institutions. ISSA supplies janitors and maintenance workers throughout the United States and is concerned with the vital role which sanitary maintenance plays in providing better public health in the United States.

The Regulatory Advisory Committee [RAC], on which I serve as Chairman, is composed of fourteen representatives from the various member companies. This membership rotates and is representative of the various interests in ISSA - manufacturers of basic chemicals, formulators and distributors. The purpose of the Committee is to advise the Board of Directors of ISSA concerning what position the Association should take with respect to legislation and regulations affecting the business activities of ISSA members. We also seek to keep members informed about the voluminous and complicated laws and regulations that relate to their business to foster compliance and avoid inadver-

tent violations. I assure you, Mr. Chairman and Members of this Committee, that we are devoted to the objective of protecting public health and the environment. Our advisory and members information program is especially important because a significant percentage of ISSA members are small businesses and most members simply cannot afford to hire an expert to keep them informed about the ever-increasing number of laws and regulations that affect their business.

Last year, I appeared before this Committee to submit testimony on behalf of ISSA concerning the Environmental Protection Agency's [EPA's] implementation of the Pesticide Act of 1978. ISSA had hoped that the EPA would take full advantage of the new provisions enacted by the Congress in 1978 to correct past mistakes and provide a reasonable and workable regulatory program for pesticides. When we testified last year we pointed out several serious deficiencies in the EPA implementation program but at that time we recognized that the EPA had had less than a year to adapt to the new provisions of the 1978 legislation.

I am sorry to report, Mr. Chairman, that although another year has passed, ISSA is faced with essentially the same problems today as we faced this time last year. I do not intend to be unduly critical of the EPA. ISSA recognizes that some of their most difficult problems have been thrust upon them by court decisions, for example, the so-called "cite-all" problem. But there are other

problems which could be quickly cured if only EPA would exercise its existing powers properly.

Mr. Chairman, I hope to provide this Committee with a concise statement of our grievances and our recommendations how to solve the problems.

First, ISSA believes the time is long overdue to correct the "cite-all" problem. EPA presently requires applicants for conditional registration of pesticides "...to acknowledge reliance on all scientifically pertinent data..." which have been submitted to EPA after December 31, 1969. (44 F.R. 27947, May 11, 1979). This mandatory cite-all applies to "...registration of a technical-grade or manufacturing use product." (id.) Although EPA purports to allow an alternative method of supporting a registration application for a formulated end-use product (id.), in practice EPA's Office of Pesticide Programs [OPP] has vacillated and frequently requires cite-all.

Under EPA's mandatory cite-all an applicant must write to all parties who have referenced any of the active ingredients in the formulation and offer to pay. Even for comparatively simple formulae this frequently entails writing more than a thousand letters. EPA has acknowledged that the resulting "transaction costs" are substantial, especially for end-use formulations (id.). In addition to these "transaction costs," this system creates multiple contingent liabilities for the applicant which is a seri-

ous deterrent to developing new products.

ISSA believes mandatory cite-all is unlawful under the present terms of Section 3(c)(1)(D) which clearly provides for alternative methods of supporting an application, i.e., supplying the applicants' own test data or citation "...of data that appears in the public literature or that previously had been submitted to the Administrator..." between the period December 31, 1969, and September 30, 1978.

Moreover, Section 3(c)(1)(D)(ii) requires the applicant to make an offer to compensate the original data submitter, not everyone who has referenced the substance during the pertinent time period. However, because of the inadequacy of the EPA filing system it is not possible to identify original data submitters. EPA formerly overcame this problem by publishing in the Federal Register a notice that an application has been filed, a listing of the active ingredients, and the original data submitters had the burden of coming forward and establishing that compensation was due. This method was declared unlawful by the U.S. District Court for the Western District of Missouri on the ground that 3(c)(1)(D) contemplates a specific offer of compensation made by the subsequent applicant to the original data submitter. [Mobay Chemical Corporation v. Costle, 447 F.Supp. 811, at 822]. The Court noted that EPA does not maintain an "indexing system" that enables that applicant to identify the original data submitter,

but held that it lacked power to direct EPA to do so and concluded that Congress should act to rectify the situation [id.].

ISSA recognizes that the primary purpose of these hearings is to consider extension of EPA's authorization under FIFRA rather than considering new legislation. However, a simple amendment to Section 3(c) (1) (D) (i) could correct the cite-all situation. This amendment would be in the nature of a technical correction made necessary by the court decision. The technical correction would simply make possible the implementation that Congress originally intended by restoring the Federal Register notification system. We earnestly hope the Committee will give favorable consideration to this proposal.

A second major problem is the EPA's misuse of its powers under Section 3(c) (2) (A). This Section clearly directs the Administrator to publish guidelines that specify the data required to support registration of pesticide products and directs that these guidelines be kept up to date and abreast with scientific progress. Section 3(c) (1) (B) also empowers the Administrator to require additional new data to support existing registrations. This assures that even registered products must be subjected to newly discovered tests to obtain up-to-date scientific information concerning their effect on public

health and the environment.

Over the past three years the EPA has been developing a variety of new guidelines under this statutory authority, which are intended to supplement the last guidelines which EPA adopted pursuant to rulemaking requirements imposed by the Administrative Procedure Act [40 CFR Part 162, Subpart A, July 3, 1979]. Some, such as Subpart F, Hazard Evaluation: Humans and Domestic Animals, have been proposed in the Federal register. Some, such as Subpart G, Efficacy Guidelines, have merely appeared in draft form.

The problem is that the EPA imposes many of these data requirements on applicants for registration regardless of whether the Guidelines are final, proposed or merely in draft form. This creates great confusion, substantial delay, unnecessary expense and a good deal of unnecessary animosity on the part of small companies who feel they are being given the run-around by big government. A good example of this abuse involves a member of ISSA who sought to register an antimicrobial product and after a year of delay, was told in writing by EPA that if certain tests were done, registration would be granted. The company had the tests conducted by a prominent medical school, but when the results were submitted to EPA, EPA requested still further tests concerning efficacy.

This places a company, especially a small company, in the position of having to abandon the product and cut

its losses, because even if they spend the additional money for the new efficacy tests, they have no assurance EPA will not require additional data before granting registration.

I want it clearly understood that ISSA does not oppose submission of adequate data to enable the EPA to do its job. Our interpretation of 3(c)(2)(A) is that an applicant for registration need only supply the data set forth in EPA's final guidelines on the day the application is filed. If EPA devises additional data requirements after that date, EPA must utilize 3(c)(2)(B) to get these new data to support the registration, but is not empowered by the law to delay grant of the registration and make submission of the new data a condition precedent to granting registration.

We believe the law as presently written is adequate, but we hope this Committee will include in its Report, a clarification that sustains our interpretation and a direction to the EPA that it conform its registration practice to the clear purport of the law.

Our third problem also relates to data requirements. In our testimony last year, we applauded Administrator Costle's statement,

...it has become increasingly clear that we are spending far too much time on individual end-use formulation applications, and that the whole structure for registration needs to be focused primarily on the chemicals

themselves rather than thousands of individual applications for products containing mixtures of chemicals.

It was on the basis of this statement, inter alia, that Congress enacted the "Simplified Procedures" and exemption provisions set forth in §3(c) (2) (C) and (D) of the 1978 Act. The intent of Congress was made quite clear:

This streamlined approach is contrasted to the existing process that treats each registered product independently, with a concomitant repetition of active ingredient review and evaluation. Generic registration will permit the 4,200 businesses engaged in formulation or labeling of end-use products to submit simplified applications to EPA, and will relieve them of responsibility to offer to pay for the registration data submitted by suppliers of technical material [except in the price structure of the technical material].

Shortly prior to enactment of the above simplified provisions, the EPA had issued proposed Guidelines which would impose on formulators six testing regimes involving acute toxicity tests:

FORMULATED PRODUCT

- Acute oral toxicity -- Section 163.81-1
- Acute dermal toxicity -- Section 163.81-2
- Acute inhalation toxicity -- Section 163.81-3
- Primary eye irritation -- Section 163.81-4
- Primary dermal irritation -- Section 163.81-5
- Dermal sensitization -- Section 163.81-6

The above-noted list of tests that would be required of formulators is, however, by no means all of the testing and data requirements the proposed guidelines would impose on formulators. In addition to the aforementioned six test protocols (multiplied by the use dilution formulations), the proposed guidelines would impose:

1. Subchronic oral dosing studies, §163.82-1, provides that such studies will be required for manufacturing-use and formulated products if use of the product is likely to result in repeated human exposure through the oral route. This could be construed by EPA to apply to sanitizers used in kitchens, on food contact surfaces and on dishes.

2. Subchronic 21-day dermal toxicity studies (§163.82-2) or Subchronic 90-day dermal toxicity studies (§163.82-3). Under the proposed guidelines, the 21-day test would be required of manufacturing-use and formulated products if its use is likely to result in repeated human skin contact. This could be construed by EPA to include a housewife or maintenance worker who uses a toilet bowl sanitizer on a weekly basis. The 21-day test is not required if the 90-day tests are done. The 90-day test requirement would be triggered by use, for example, of chlorine in a swimming pool.

3. Chronic feeding studies, §163.83-1, provides that "all pesticides involving repeated exposure are sub-

ject to this data requirement". [Emphasis added] It specifically provides that the requirement applies to manufacturing-use and formulated products and cites examples of use including, inter alia, in and around residences, swimming pools, and in enclosed working places or their immediate vicinity.

4. Oncogenicity studies, §163.83-2, would require such tests of manufacturing-use and formulated products if the product is likely to result in human exposure over a portion of the human life span which is significant in terms of either the time the exposure occurs (e.g., dippers) or the duration of exposure (e.g., swimming pool additives or indoor use pesticides in aerosol form).

5. Teratogenicity studies, §163.83-3, would require such tests of manufacturing-use and formulated products which may reasonably be expected to result in significant exposure to human females (e.g., a woman using sanitizing products).

6. Reproduction studies, §163.83-4, would require such tests of manufacturing-use and formulated products if the product is likely to result in significant human exposure to the product.

7. General metabolism studies, §163.85-1, would require such studies of manufacturing-use and formulated products if the product required a chronic feeding study or an oncogenicity study discussed supra.

8. Domestic animal safety tests, §163.86-1, would require ten tests related to domestic animals if domestic animals are exposed to either manufactured or formulated pesticide products.

Last year ISSA made the point that the EPA should revise the proposed Guidelines to remove the requirement that formulators of end-use products conduct the foregoing chronic and subchronic tests provided, of course, that such tests have been conducted by the manufacturer of the basic pesticide chemical utilized in the end-use formulation.

ISSA has filed two formal written requests to the EPA seeking to rectify this situation and met with EPA officials in October of 1979 requesting relief. The EPA position appears to be that it does not intend to enforce these chronic and subchronic data requirements upon formulators of end-use products at the present time, but it refuses to amend the language of the proposed regulations. We respectfully submit that it is poor regulatory policy to propound regulations that say one thing, when in fact, the agency operates differently. We therefore hope this Committee will direct the EPA to conform its Guidelines to be consistent with existing law.

Finally, ISSA contends that the EPA's present method of processing applications for Supplemental Registrations can be simplified, expedited and done at substantially

less cost without interfering with the objective of the Act to protect public health and the environment. A Supplemental Registration is the registration of an already tested and registered end-use product which is packaged by the registrant but sold by distributors of the registrant under the distributor's product name. The contents of the product sold by the distributor is the same as the product registered by the registrant. The only difference is the name, and the label of the distributor's product clearly references the original EPA registration number.

Under current EPA practice, an applicant for a Supplemental Registration is required to fill out an EPA form which requires disclosure of the product registration number, the distributor's EPA number, the name and address of the registrant, the product name, the registrant's signature, the distributor's name and address, the distributor's proposed product name and the distributor-applicant's signature.

The EPA usually takes six to eight weeks to process this application. In some instances this process takes substantially longer and during the summer and fall of 1979 a substantial delay period was usual.

ISSA respectfully submits that the EPA has legal authority and should in the interest of efficiency allow applicants for Supplemental Registrations to simply send notification to EPA setting forth the above information

and immediately begin to market the product without waiting for EPA processing. This procedure would save substantial agency resources and facilitate the marketing of already registered products.

Mr. Chairman, ISSA appreciates this opportunity to bring to the Committee's attention the foregoing measures which if adopted would substantially improve pesticide regulation. Only the cite-all problem requires a legislative change, but as I pointed out, the change is essentially a technical correction to achieve the original intent of Congress and would not open up any complicated or time-consuming debate.

The other recommendations can, we believe, be adopted by EPA without legislative change. We hope this Committee will direct in its Committee Report that the EPA adopt these changes.

Thank you.

Mr. DE LA GARZA. Next we have Mr. Dadekian.

Your full statement, likewise, will appear in the record. If you care to summarize it, that would be perfectly agreeable to us.

**STATEMENT OF ZAVEN A. DADEKIAN, VICE PRESIDENT,
LONZA CHEMICALS, INC.**

Mr. DADEKIAN. Thank you, Mr. Chairman.

My name is Zaven Dadekian. I am a vice president of Lonza, Inc., a manufacturer of basic antimicrobial chemicals, headquartered in New Jersey with plants in Rhode Island, Georgia, Illinois, Texas, and California.

I want to express my appreciation for this opportunity to testify about three major problems the pesticide industry faces as a result of EPA's implementation of FIFRA.

At the outset I want to emphasize that EPA has made progress and I do not want to appear unduly critical. However, these three problems are very important and EPA should correct them with the help of this committee and the Congress. I have a detailed prepared statement which I would like to submit for the record and devote my time today to giving you concrete examples of just how serious these three problems really are.

First, with respect to the cite-all problem, in my prepared statement I set forth the detailed legal and other reasons why mandatory cite-all is illegal and inefficient and propose a simple way to correct the problem.

However, let me point out what in my judgment is the most damaging aspect of cite-all. EPA refuses to allow manufacturers of basic pesticide chemicals to rely on their own scientific data to support registration of a new product. Instead, it requires manufacturers to adopt cite-all and thus rely upon all pertinent data cited between the end of 1969 and 1978. I respectfully submit that EPA's cite-all policy thereby discourages manufacturers of basic chemicals from generating the best and latest scientific data and instead compels them to cite what may be obsolete data generated by outmoded testing procedures which are therefore of doubtful validity. Mr. Chairman, I think this situation requires correction.

My second example relates to the EPA misinterpretation of section 3(c)(2)(A) which is discussed in detail in my prepared statement. The practical effect of the EPA policy is that a company that desires to develop a new product cannot know in advance all of the data requirements EPA will require for registration of the product. At present the EPA enforces a hodgepodge of data requirements derived from 1975 guidelines, from various provisions in their proposed guidelines, and even requirements that appear only in draft guidelines that have not even been published in the Federal Register.

As a practical matter, Mr. Chairman, and I speak from actual experience, many valuable products are being developed or are being delayed because you cannot forecast development costs, and perhaps even more important, the time involved. This happens because EPA changes the rules of the game so frequently in the course of processing a registration application that it is impossible to forecast what data requirements will ultimately be imposed on a new product.

Lonza actually delayed developing its improved Bardac Line of anti-microbial manufacturing-use products for several years because we could not be sure what the data requirements would be and hence what they would cost, as well as how long it would take to actually register products for ourselves and our customers.

Ironically, this new line of products is far better than existing products from an environmental and public health point of view. This EPA policy is bad for the industry, bad for the economy, and bad for the environment. My detailed statement sets forth our recommended solution to the problem.

Finally, my prepared statement explains the adverse consequences of EPA's mishandling of the so-called inert active ingredient problem. This relates to substances which are used as solvents, builders, or chelating agents in pesticide products but which are not themselves pesticides and no pesticidal claim is being made or is intended concerning them.

EPA nonetheless treats them as if they were active ingredients in a pesticide even though as a scientific matter they are inert. My prepared statement challenges the legality of this EPA practice and details the hardship it causes both for industry and the EPA itself.

However, Mr. Chairman, the most objectionable aspect of this practice is that it is a flagrant case of double regulation. The EPA has clearly stated it regulates these substances under the Toxic Substances Control Act, yet it continues to regulate them under FIFRA. We believe this also should be promptly corrected.

Mr. Chairman, appendix B of my prepared statement sets forth proposed corrections to the first two problems—the cite-all problem and the ever-changing data requirements. These would involve minor technical amendments to FIFRA. I am aware that the committee does not want to become involved in far-reaching and major controversial amendments to FIFRA. However, the amendments I propose are in the nature of technical, correcting or clarifying amendments and I hope you will consider them. These minor changes would make a major contribution to achieving a fair and efficient pesticide registration program.

Thank you.

Mr. DE LA GARZA. Thank you very much, sir.

Mr. Fithian?

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

Mr. Dadekian, we have a bell so I will have to be very brief. If you could be brief, I think we can finish this up.

Think for a moment about the other side of the cite-all question. I asked the Administrator earlier whether it was or was not a protect-thy-flanks movement on their part. I think a lot of reasonable people could say that it probably is.

Think also, that it was industry which insisted on data which it generated and provided EPA originally which got somebody to the point where they figured that they had better cite everything on the books down there and, if that is used to justify the use of a pesticide, pay you because you ran some rat tests somewhere back upstream.

My question is this. Everybody wants to get out of the cite-all business. I believe EPA wants to. This committee wants to and industry wants to. Would your company be willing to sign off on a letter saying

that you would not bring suit against the Government if they failed to compensate you if someone else provided data in the same area that you did in support of their application for registration?

Mr. DADEKIAN. Our position is not that cite-all has no place. Cite-all does have a place and we do have sympathy for the EPA's approach. Our objection is that they require mandatory cite-all.

In some cases in a registration, particularly of a new product, only new data is pertinent, not old data.

Mr. FITHIAN. Then my question would apply to the old data and my question still stands. Would you be willing to sign a letter to the EPA on behalf of your company saying you would not bring suit against the EPA if they cited only the application and the new materials supplied by some other company?

Mr. DADEKIAN. No; we would not.

Mr. FITHIAN. All right. Then let me just say to you and to everybody here from the industry: Please understand the problem that you are putting all of us in. That is precisely the legal, monetary problem.

Mr. DADEKIAN. Mr. Fithian, I just want to expand on that. There are cases where the cite-all approach that the EPA is taking is pertinent and valid. Our suggestion is that not all cases fall into that category and where one does not an alternative method ought to be available to industry. In cases where cite-all is required we suggest that the EPA streamline its procedures so that it puts less of a burden on industry to comply with their regulations.

In particular, we do not like the notification by hundreds of letters to people obviously having no data. Little mom and pop stores which have pesticide products must be approached with very formal letters by major companies asking whether they are looking for compensation from a major company. These people could say yes with no basis.

Perhaps they did not even understand the letter that came to them. Then an executive, a top flight executive, must enter into negotiations with these people—

Mr. FITHIAN. I understand, but if I may just interrupt. This is the warning bell so we have 10 minutes left.

From a practical point of view, in fact, it has been my experience that EPA is running scared down there. When you run scared you are not very efficient. You do everything to protect your flanks and they do overregulate. They overregulate you and they respond to your group and they respond to the suits from the environmentalists and all these sorts of things.

Just for one moment I would ask you, as a representative of industry, to put yourself in Doug Costle's position and say, "You have to protect the U.S. Government from suits."

There have been enough suits launched by industry to raise a serious question as to whether or not industry is not bringing on the inefficiencies, the ineffectiveness, the duplication, the lack of registration, and all the other things. That is the burden of the testimony that these guys will give you.

When I look at those lawsuits and the money and time involved in them, I have to say they have a point. You just have to. There is no alternative to it.

What I am looking for is a practical way out. I am just asking you—later on we will ask Dr. Early and his group—whether or not there is

any willingness on the part of industry to come forth and say, "Look, we do not want the burden of cite-all and therefore we are willing to give up something." The giving up of something is a potential for suit against the Agency.

Do you follow my line of thinking?

Mr. DADEKIAN. Yes.

Mr. DE LA GARZA. Thank you very much, sir. We appreciate your presence here.

We will have a 10 minute recess while we cast our votes.

[The prepared statement of Mr. Dadekian follows:]

STATEMENT OF ZAVEN A. DADEKIAN, VICE PRESIDENT, LONZA, INC., FAIR LAWN, N. J.

Mr. Chairman, my name is Zaven A. Dadekian. I am the Vice President of LONZA, Inc. whose address is 22-10 Route 208, Fair Lawn, New Jersey 07410. LONZA manufactures basic antimicrobial raw material chemicals, formulates such chemicals into end-use products and distributes these antimicrobial products in commerce. I appreciate this opportunity to appear before this committee to testify concerning certain major problems we are having with EPA's administration of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended in 1978.

Mr. Chairman, we have three basic problems with the EPA's implementation of FIFRA:

1. Cite-all. The first problem is one which I am sure you have heard about from virtually every sector of the pesticide industry. I have reference to the "cite-all" problem. I am sure that you are all acquainted with EPA's "cite-all" policy. The EPA has clearly declared its intention to continue to impose "cite-all" on the registration of manufacturing use products. (44 F.R. 27935, May 1, 1979.) I will discuss "cite-all" as it effects registration of end-use products in a moment.

LONZA objects to "cite-all" for the following reasons:

A. "Cite-all" is illegal. Section 3(C)(1)(D) clearly provides that applicants may support a registration by "...a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator...". EPA is clearly exceeding the powers delegated by Congress when it refuses to accept the applicant's own data as the sole method of supporting his

registration for a manufacturing use chemical and imposes mandatory "cite-all".

B. "Cite-all" precludes use of the latest and best scientific data in the registration process. If manufacturers of basic pesticide chemicals were allowed to generate and rely on their own data, this testing would employ the latest and most sophisticated protocols and would produce the best available scientific data upon which the EPA could base its registration program. Instead, imposition of "cite-all" means that much of the data cited was developed by obsolescent methodology which does not represent the best data the state of the art can provide. The crowning irony, Mr. Chairman, is the fact that EPA acknowledges it is not going to consider and evaluate the cited data anyway. (44 F.R. 27934, May 11, 1979.) We submit this subverts the clear purpose of FIFRA that EPA use the best available scientific data in its registration program.

C. "Cite-all" interferes with innovative competition by penalizing firms that seek to introduce new products. "Cite-all" not only requires citing all references to active ingredients in a new product but also requires notification and offers to compensate all those who have referenced these substances in prior registrations. Given the chronic delay in the EPA registration process, this puts competitors on early notice that you are about to introduce a new and improved product. The competitive edge that comes from product innovation is the chief incentive to develop and introduce new and better products. If that competitive edge is destroyed by premature disclosure of the of the manufacturer's intent to introduce a new product, you have

created a major deterrent to product innovation. LONZA submits this is against the public interest.

D. "Cite-all" imposes unnecessary transaction costs on the pesticide industry, especially on end-use products. Last year LONZA submitted as Appendix A to its testimony an exhibit which demonstrated that an applicant for registration of a commonly marketed disinfectant/sanitizer cleaner would have to send 1,166 notices and offers to compensate to all those who had referenced any of the listed ingredients. EPA acknowledged that this entailed excessive transaction costs and undertook two measures to improve the situation. First, for a time EPA allowed manufacturers of end-use products to use the so-called "alternative method", i.e. to develop and use their own efficacy and toxicity data or to cite a specific set of data pertaining to an identical formulation. After a few months, EPA discontinued allowing the use of the "alternative method" except in cases of formulations utilizing a registered active ingredient and inert ingredients. In cases where the formulator uses substances which are scientifically inert (such as chelating agents, solvents and detergent builders) EPA treats certain of these substances as active ingredients for regulatory purposes and does not allow use of the so-called "alternative method". This latter category encompasses a majority of the one-step cleaner/antimicrobial products. Secondly, EPA, through much diligence and hard work, has revised the original "Submitters list" to eliminate patently inappropriate references. LONZA has updated its Appendix A, which is appended to this statement, and today an application for registration of the subject product would entail notice and

offers to compensate somewhat more than 200 submitters instead of 1,166. This is undeniably progress in terms of reducing transaction costs but the "cite-all" system still involves substantial waste.

In addition, "cite-all" exposes the applicant to contingent liability to compensate all those to whom an offer to compensate is sent. This system opens the door to spurious claims for compensation by submitters who are not original data submitters. Section 3(C)(1)(D)(ii) clearly creates a legal duty to compensate only "original data submitters". The problem is that under the EPA system there is no indexing system to identify who the original data submitters are. The EPA formerly resolved this problem by publishing in the Federal Register applications for registration listing the active ingredients contained in the product. This method was declared unlawful by a Federal Court which construed FIFRA as requiring direct, personal notification and negotiation with the original data submitter. The court acknowledged that this interpretation created a "catch 22" situation inasmuch as there is no way to identify original data submitters, but indicated that it was up to EPA or the Congress to correct the situation.

Mr. Chairman, LONZA has a simple solution to this problem. I am aware that the Committee is primarily concerned with the extension of authorization of FIFRA and does not desire to consider complicated or controversial amendments to FIFRA at this time. However, the amendment we propose is really in the nature of a technical correction to overcome the Court's interpretation of FIFRA and in effect to carry out the original intent of Congress. This "perfecting" or "corrective" amendment is set forth in

Appendix B of this testimony and I earnestly urge you to consider its enactment at this time.

II. Data requirements for registration. Our second major problem with the EPA is the manner in which it enforces Section 3(C)(2)(A) of FIFRA, which provides that the Administrator publish guidelines specifying the kinds of information which will be required to support registration and to revise such guidelines from time to time to keep them abreast of scientific and technical progress. The present guidelines were made final on July 3, 1975, and are set forth in 40 CFR Part 162, Subpart A. However, in the period since these guidelines were made final, EPA has published several proposed revisions in the Federal Register and has informally released draft guidelines that presumably will be published in the Federal Register at some future date. None of these proposed or draft guidelines have been made final. However, the EPA frequently requires applicants, as a condition precedent to registration, to supply data and undertake testing that is listed in the proposed and draft guidelines. LONZA believes that this practice is contrary to law. LONZA acknowledges that the EPA is entitled to new data not required in its final guidelines, but only under the terms of Section 3(C)(2)(B) which provides that if the Administrator determines that additional data (i.e. data additional to that required by its final guidelines) are required, that he is empowered to require such data to support an existing registration. In other words, we believe the law provides that if an applicant for registration satisfies the data requirements specified in the final guidelines, he is entitled to registration subject to

supplying subsequent new and additional data to support the registration. In practice, EPA withholds registration until not only the final guidelines are satisfied, but the new requirements contained in the proposed and draft guidelines are also satisfied. As a result, the pesticide industry is faced with confusing and constantly changing data requirements which frustrate orderly product development planning and result in unnecessary delay and cost.

I want to emphasize that LONZA is willing to provide any data reasonably necessary for EPA's regulatory purposes, but we believe that the law provides a system whereby we can know what the data requirements for registration will be. If EPA wants data additional to that contained in its final guidelines, it can obtain that data under the authority of 3(C)(2)(B) as data necessary to support an existing registration rather than impose the requirement as a condition precedent to granting a registration.

LONZA believes that the present law upholds our position, but to date EPA continues to require any data it feels may have some justification regardless of what the final guidelines provide and withholds registration until such data is supplied. To clarify this situation, we have proposed a brief one sentence amendment in Appendix B to this testimony. Once again, the proposed amendment is strictly limited to clarification of Congressional intent with respect to Section 3(C)(2)(A) and I earnestly urge you to consider its enactment at this time.

111. The Inert "Active" Ingredient problem. The pesticide industry commonly uses certain substances such as isopropol

alcohol, ethanol, sodium metasilicate, sodium carbonate, tetrasodium EDTA, etc. in antimicrobial products to function as a solvent, builder or a chelating agent. No pesticidal claim is either made or intended with respect to these substances. Scientifically speaking these substances are inert.

Nevertheless, the EPA treats these substances as if they were in fact active ingredients. The consequences of this regulatory policy are two-fold: (1) it increases the number of required notices and offers to compensate that an applicant must send under EPA's "cite-all" policy; and (2) it increases the data requirements that must be satisfied under EPA's current guidelines. Thus, this policy of treating inert ingredients as active ingredients results in substantial unnecessary cost and effort.

LONZA contends that because these ingredients are not represented or intended to be pesticides, that EPA cannot lawfully impose regulatory requirements upon the use of these ingredients under FIFRA. Moreover, as the following Federal Register publication notes, EPA itself formally acknowledged that these substances are more appropriately regulated (and are in fact already regulated) under the Toxic Substances Control Act (TSCA) of 1976:

"The Administrator agrees that raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA. In order to be considered a pesticide, a substance must be intended for use as a pesticide. Raw materials, intermediaries and ingredients produced or used in the manufacture of pesticides are not themselves

regulated under FIFRA (unless they happen to be pesticides themselves) and therefore are subject to TSCA." (42 F.R. 64586, Dec. 23, 1977).

Accordingly, LONZA respectfully requests that this Committee direct the EPA to discontinue its present practice of double regulation and indicate that regulation of these substances under FIFRA is unlawful.

Once again, Mr. Chairman, I appreciate this opportunity to present these problems to the Committee and respectfully request that the Committee take the actions I have heretofore discussed.

APPENDIX A
(updated)

Conditional Registration for a Disinfectant/Sanitizer
Cleaner based on EPA PR Notice 78.5 - Option 3

<u>Component</u>	<u>Data Submitters</u>	
	(First Edition) ¹	(Third Edition)
Antimicrobial	204	46
* Tetra sodium ethylene diamine tetraacetate	280	51
* Sodium carbonate	233	38
* Sodium metasilicate	158	25
Isopropyl alcohol	291	55
	1,166	215

* detergent builders

¹ This would require that 1,166 offers to pay compensation letters be written by a formulator at a cost of approximately \$ 10.00 per letter : \$ 11,660.00

APPENDIX BTo effect the "Cite-all" correction:

In Sec. 3(C)(1)(D)(i) insert before the final "Provided," the following:

a period (.) after "pesticides" and add the language:

For purposes of this paragraph the Administrator shall publish registration applications in the Federal Register disclosing the active ingredients contained in the product for which registration is sought, and such publication shall be legal notice to the original data submitter who shall verify his status as original data submitter or waive his rights to requirement of written permission under this section.

In Sec. 3(C)(1)(D)(ii) insert after the first sentence (ending with the word "offer.") the following:

For purposes of this paragraph the Administrator shall publish registration applications in the Federal Register disclosing the active ingredients contained in the product for which registration is sought, and such publication shall be legal notice to the original data submitter who shall verify his status as original data submitter or waive his rights to compensation for use of said data.

To solve the "open-ended data requirements" problem:

Insert after the first sentence in Sec. 3(C)(2)(A), (ending with the word "time") the following sentence:

"Applicants for registration of pesticide products shall supply only such data as specified in guidelines in force and effect on the date said application is filed with the Administrator.

Mr. DE LA GARZA. The subcommittee will be in order.

Our next witness will be Dr. Rupert Cutler, Assistant Secretary for Natural Resources and Environment of the U.S. Department of Agriculture.

STATEMENT OF M. RUPERT CUTLER, ASSISTANT SECRETARY, NATURAL RESOURCES AND ENVIRONMENT, U.S. DEPARTMENT OF AGRICULTURE; ACCOMPANIED BY DAVID A. GRAHAM, ACTING ASSISTANT DIRECTOR, PEST MANAGEMENT AND TOXIC SUBSTANCES, OFFICE OF ENVIRONMENTAL QUALITY; AND STANLEY R. FERTIG, CHIEF, PESTICIDE IMPACT ASSESSMENT, SCIENCE AND EDUCATION ADMINISTRATION, AGRICULTURE RESEARCH

Mr. CUTLER. Thank you, Mr. Chairman. It is a pleasure to be before you again, this time on H.R. 7018, to extend the Federal Insecticide, Fungicide, and Rodenticide Act until September 30, 1981.

The Department of Agriculture has a strong interest in the regulation of pesticides from two aspects. We are deeply concerned about crop and forestry production and animal protection. We are concerned about human health and safety and about the health of our natural and urban environment as well.

In 1976, about 1 billion pounds of active chemical ingredients were used in the United States. Farm use accounted for about 600 million pounds. Of this amount, herbicides, defoliants, and desiccants accounted for 410 million pounds. Farmers used 208 million pounds of insecticides, miticides, and fumigants, and 43 million pounds of fungicides.

More recent nationwide pesticide use information has not been compiled—we hope to see pesticides use surveyed every 5 years in the future—but it appears that current use is somewhat higher.

Efficient regulation of pesticides is essential to protect man and his environment and to maintain adequate supplies of food and fiber. The use of pesticides, as part of our arsenal of integrated pest management tools, will continue to be necessary in the foreseeable future for the production of food, feed, and fiber to meet domestic and export needs.

We, in the Department of Agriculture, work closely with the Environmental Protection Agency in the implementation of the Federal Insecticide, Fungicide, and Rodenticide Act. One area of cooperation is the rebuttable presumption against registration process.

To participate effectively in this process the USDA established in 1976 a national agricultural pesticide impact assessment program. The purpose of the program is to provide the most objective and accurate data available for defining and evaluating the benefits and risks of selected pesticides having critical agricultural and forestry uses.

Our national pesticide impact assessment program assesses the value to agriculture and forestry of pesticides identified by the Environmental Protection Agency as possibly posing hazards to human health or the environment. The program has been successful. The Environmental Protection Agency has utilized the information so developed in its regulatory decisions.

The USDA's national agricultural pesticide impact assessment program is a multiagency effort. It taps the expertise of pesticide special-

ists employed by the Animal and Plant Health Inspection Service; the Economics, Statistics, and Cooperatives Service; the Forest Service; the Science and Education Administration; the Office of the General Counsel; and State agriculture experiment stations, extension services, and departments of agriculture.

Close cooperation with the Environmental Protection Agency is provided for. Coordination among USDA participants is effected by our Office of Environmental Quality through a steering committee and a technical advisory group. The Office of Environmental Quality also has the lead responsibility for departmental liaison with the Environmental Protection Agency.

The USDA established this program with redirection funds of \$2.2 million. Subsequently, a fiscal year 1977 supplemental budget request of \$5.2 million was approved by Congress to augment the program and an additional \$1 million for distribution to State cooperators by Extension was added in fiscal year 1979. Funding has continued at this level to the present.

Since the start of the program the USDA and its cooperators have established assessment teams for 26 pesticides which have been in the Environmental Protection Agency's rebuttable presumption against registration process and we have formed an additional five assessment teams for which rebuttable presumptions have not yet been issued. The EPA has told us that there is a high likelihood that RPAR's will be issued on these five pesticides.

The reports from these teams have been or are being used in the Environmental Protection Agency's decisionmaking process to formulate regulatory decisions. These reports have been the focal point for extensive interactions among our staff and the Environmental Protection Agency's staff, the Scientific Advisory Panel to the Environmental Protection Agency, environmental groups, user groups, and the pesticide industry. Our reports and the ensuing dialog have helped identify the benefits and potential risks, coupled with exposure, of pesticide use. These coordinated efforts have identified ways to minimize the risks.

To generate the information required by the assessment teams several new research activities—lab experiments, field trials, and other studies—have been initiated. These have been short-term, information-gathering projects targeted to improve our knowledge on efficacy, crop yields, and crop quality. More than 300 such short-term investigations have been funded.

It has become increasingly apparent that more information also is needed on human exposure to pesticides and on the environmental effects of pesticide use. Under our national assessment program the land-grant universities and USDA have initiated new exposure studies under various field conditions and in laboratory situations. These studies have been designed to acquire more information for specific pesticides. Information on environmental effects has been obtained in part from ongoing research programs and in part from newly initiated studies.

While the program has been successful in providing information for decisionmakers and has promoted reasonable and responsible decisions, several areas require improvement. We have found the scope and depth of analyses required our involvement in litigation, and the number

of pesticide assessments have been greater than we anticipated. The biological information required to make assessments has not been as available as anticipated. In addition, demands for expanded information on pesticide use, risk of human exposure, and related information have increased over time.

To meet these needs we plan to revise and expand our USDA assessment program. Principal areas of revision and expansion will include establishing a commodity focus for obtaining biological information, assessments, pest control and exposure surveys, information systems, and exposure research. Other improvements will include better operating procedures, more uniformity in report development and preparation, and stronger working relationships with the Environmental Protection Agency.

We are developing a plan of action for this program now which will cover activities for the next 5-year period. The draft plan is being reviewed within the USDA and the Environmental Protection Agency. By this sharing of plans and initiatives by USDA and the Environmental Protection Agency duplication of effort will be minimized.

The following are what we propose:

One, assessment teams will continue to be the focal point of the program. There will be teams formed for every pesticide brought under review for which there are agricultural or forestry uses. Eight to ten team assessments will be initiated each year and there will be a carry-over of five assessment team activities initiated the previous year.

Two, pesticide assessments by commodity will be begun. This will involve obtaining information relating to yield and quality of production for varying pest control methods and projecting the economic implications of future scenarios which depict the availability of alternative pest control technologies. Two assessments will be initiated per year and completed in that year.

Three, research, monitoring, information gathering, literature searches, and related activities will be begun to gather and develop information on exposure, environmental effects, and field trials to estimate quality and yield changes for alternative pest control technologies. In these areas up to 140 such studies will be initiated per year.

Four, new pest control and exposure surveys will be expanded to provide information on agriculture, forestry, selected nonfarm rural uses, sod production nurseries, and greenhouses. The work will be spread over a 5-year period with approximately equal effort taking place in each year.

Five, the pesticide information program will be improved to provide information on pesticide registrations, recommendations, application practices, and availability of alternative controls through a national computerized data system available to individual States and other organizations.

Much of this information will be developed through the State land-grant university system. We look forward to continuing and strengthening the spirit of USDA-land-grant-university-EPA cooperation in the rebuttable presumption against registration process and to extend it, as needed, into the Environmental Protection Agency's registration standards program or other areas where the Department has,

or has access to, the expertise needed to answer questions that develop during the regulatory decisionmaking process.

Administrative hearings on pesticide regulatory decisions provide a system for publicly airing the issues involved. The USDA has participated in some of these proceedings to present the scientific knowledge which has been developed as an output of the Department's many programs and research activities.

The hearing process requires that scientific data be presented in an advocacy setting. This requirement is of concern to many scientists who wish to present their data on the subject without regard to which side or viewpoint the data may favor. Because the USDA takes a nonadversarial stance in the Environmental Protection Agency hearings, we play the important role of sponsoring scientists who want to remain relatively neutral about the ultimate regulatory decision. In these hearings USDA presents the best scientific evidence we can provide. This information can then be relied on by those outside the Department and used to support their own positions as appropriate.

In conclusion, Mr. Chairman, the Department has worked closely with the Environmental Protection Agency in the implementation of the pesticide law. By negotiation and cooperation the two agencies have resolved a number of complex and difficult problems. We expect these close working relationships to continue and to be strengthened. We support the extension of the Federal Insecticide, Fungicide, and Rodenticide Act.

Mr. Chairman, my associates and I will do our best to respond to your questions.

Mr. DE LA GARZA. Thank you very much, Mr. Cutler. I appreciate your statement and your final conclusion about the cooperation between the EPA and the Department. I am very happy to hear that.

Do you have any problem at all in having them accept your recommendations or in having them work with you to compromise in some areas that affect agriculture in general?

Mr. CUTLER. May I ask Dr. Fertig to respond to that question, sir?

Mr. FERTIG. I would not say that there are no problems, Congressman, but we have had excellent dialog with EPA in trying to resolve any issues over which there might be disagreement or misunderstanding.

Mr. DE LA GARZA. My question is: Do they accept you as the authority on agriculture if there is a question as to harm or prejudice to the agricultural process which you feel would not be related solely to environmental impacts?

Mr. FERTIG. Generally, I would have to answer, yes.

Mr. DE LA GARZA. A further question to you is this. Are you the spokesmen for agriculture in a positive way, or do they convince you otherwise?

Mr. CUTLER. We are the spokesmen for agriculture and forestry, Mr. Chairman.

Mr. DE LA GARZA. I am impressed with your assessment programs and teams. If there are areas where it would be more basically an agricultural problem—you may not be the proper level to ask this but I will ask anyway—would you be able to handle added responsibilities in relation to EPA, pesticides, et cetera?

Mr. CUTLER. The Science and Education Administration and the Forest Service both have pesticide research capability that can be expanded to the extent that resources are provided for that.

Mr. DE LA GARZA. If, by chance, there should be some changes in the law, you have the capability to accept added responsibilities in this area. Is that correct?

Mr. CUTLER. Yes; we do.

Mr. DE LA GARZA. Thank you very much, sir. We appreciate your being here and appreciate your patience in awaiting your turn.

Mr. CUTLER. We are pleased to be here.

Mr. DE LA GARZA. Thank you.

The subcommittee will be in recess subject to the call of the Chair which will be at approximately 3 p.m.

[Recess taken.]

Mr. DE LA GARZA. The subcommittee will be in order.

This afternoon we have some representatives of the GAO and a representative of the EPA. We are awaiting the arrival of my colleague, Mr. Wampler.

Mr. Jellinek, Mr. Johnson, and Mr. Wilson, why don't you come to the witness table. We appreciate your indulgence and your making yourselves available.

You have a formal presentation which we deferred this morning. As was explained then, without objection, we will include all of your statement in the record and then if you would care to give us a brief summary it would be appreciated. I regret to say that I have not had an opportunity to read your statement thoroughly.

Since you have heard and become acquainted with some of the testimony during the previous part of the hearing with relation to some of the affected parts of the industry, it would be helpful if you could address yourself to those issues as well as those in your prepared statement in case they are not covered in your statement.

STATEMENT OF STEVEN D. JELLINEK, ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY; ACCOMPANIED BY RICHARD WILSON, DEPUTY ASSISTANT ADMINISTRATOR, GENERAL ENFORCEMENT; AND ED JOHNSON, DEPUTY ASSISTANT ADMINISTRATOR, PESTICIDE PROGRAMS

Mr. JELLINEK. Thank you, Mr. Chairman. I appreciate the opportunity to appear again this afternoon.

We have attempted to answer in my testimony most of the questions raised and to address most of the major issues raised in previous portions of this hearing. My formal testimony is rather lengthy and I appreciate your indulgence in permitting me to submit it for the record. Why don't I, as you suggested, just go through some of the more important issues and leave the rest for the record.

I, frankly, think it would be worthwhile to review the section on cite-all, since that was one of the major subjects of controversy earlier in this hearing.

In the earlier hearings spokesmen for the National Agricultural Chemical Association and the Chemical Specialties Manufacturers

Association, in their testimony, took issue with the Agency's regulations issued in May 1979. The regulations in some cases require applicants for registration to offer to pay compensation for all the data that is relevant to the safety of an active ingredient of a pesticide product.

Our reasons for issuing these regulations are detailed in a 10-page letter to Senator Stewart, Chairman de la Garza's counterpart subcommittee chairman, dated February 11, 1980, which was made available some time ago to the committee staff. A copy of that letter is attached to my prepared testimony for the convenience of the subcommittee members.

As we indicate in that letter, in 1977 and 1978 the Agency made clear to Congress our intent to review all relevant data in preparing the registration standards which we will use as the principal basis for unconditional registrations under section 3(c)(5) in the future.

We also note that FIFRA section 3(c)(7) expressly requires conditional registration applicants to rely for data compensation purposes on the same data that would be required for a section 3(c)(5) registration.

NACA has indicated they will propose a system under which one, an applicant would tell us which data he wanted us to consider "in support of" his application, and two, we could look at whatever other data we felt necessary "so long as (the other data) are not used (by EPA) to affirmatively support" the application.

This proposal is the same one that was advanced by NACA to us last summer. At that time we told them that their approach had two fundamental flaws that precluded its adoption.

The first was that the NACA approach would not work in cases where we do consider all relevant data before deciding a product could be registered or reregistered—that is, when we develop a registration standard—because, as the courts have noted, our scientists cannot pretend to forget part of the data for the convenience of applicants and also because the whole reason for using a generic approach to registration is to get away from the same inefficient, duplicative review of portions of the data base that the NACA approach would require.

The second flaw is that the NACA approach would not work in cases where we do not consider all relevant data before deciding a product can be registered—that is, all the conditional registrations now being issued under section 3(c)(7) (A) and (B)—for the simple reason that under the NACA approach EPA would have to review all the data the applicant puts before us, on an ad hoc basis, for the sole purpose of deciding whether he had submitted enough data to avoid a claim by some other data owner that the latter's rights had been violated.

Conditional registration of "me too" products and of new uses for old products expressly contemplates that we will not review data on existing uses. The idea is that we can use our resources better in the development of registration standards and other tasks and should not hold up marketing of "me too" products or new uses pending ad hoc reviews of data on existing uses.

Another issue that came up at the previous hearings involved trade secrets. Once again, NACA is concerned that the FIFRA authorizes disclosure of proprietary data which the pesticide-producing in-

dustry considers to be trade secret. Disclosure of such data, NACA argues, "destroys valuable private property" and permits unfair and injurious competition within the pesticide industry.

When Mr. Costle appeared before this subcommittee in 1977 one of the most important and controversial issues he addressed was that of trade secrets. There are two basic issues: One, what data may be used by any pesticide producer to support product registration, and two, what data should be accessible to the public.

EPA's long-held position which Congress affirmed in enacting the 1978 amendment is that information about health effects should be available to the public. We should withhold from public scrutiny a narrowly limited class of information, primarily manufacturing and quality control data and confidential formulas.

The mandatory data-licensing scheme created by section 3(c)(1)(D) substitutes one system of protection for data—that is, compensation and exclusive use—for that which the industry has always preferred—secrecy. At the same time the act's carefully balanced data scheme takes into account societal goals other than protection of proprietary interest.

The compromise which yielded the current law took account of desirability of promoting the sharing of data development costs within the producing industry and the value to farmers and consumers of encouraging healthy competition and access to the marketplace for firms who do not develop their own data. The law also provides, through the exclusive-use provision, for special protection of data during the early years of a chemical's life, rewarding innovation and permitting rapid recovery of investment costs.

As Mr. Costle said this morning, we continue to strongly support the compromise that resulted in the 1978 amendments' treatment of trade secrecy and we hope and expect that our interpretation of that compromise will survive the court challenges that the industry has mounted against it.

Another subject that came up at the earlier hearings was the registration standards program. Both NACA and CSMA assert EPA has failed to implement the simplified procedures for registration required by the amended FIFRA, section 3(c)(2)(C) and (D), since the registration standards program is not yet fully underway nor will it be complete for at least 10 or 15 years. Specifically, section 3(c)(2)(C) and (D) exempts any applicant for registration of an end-use product from the compensation requirement imposed by section 3(c)(1)(D) for data which pertain to the safety of the basic active ingredient already registered by EPA which the applicant purchases from another producer and uses in formulating his product.

Of course, section 3(c)(2)(D) was effective upon amendment and we have conducted our program accordingly. Data requirements for registration have been set in accordance with section 3(c)(2)(D). Registrants of end-use products have not been required to perform chronic or subchronic hazard evaluations for end-use products formulated from registered manufacturing-use products.

Moreover, the Agency has also prescribed the required simplified procedures for registration in the interim final regulations governing conditional registration and compensation for use of data published by May 11, 1979, 7½ months after enactment of the amendment.

Section 162.9-7 of the interim final compensation regulations specifically addresses this exemption. Subsection (a) of that section states the terms of the exemption under FIFRA; subsection (b) defines data pertinent to the safety of a purchased product; subsection (c) defines the term "end-use product"; and subsection (d) clarifies that the 3(c)(2)(D) exemption does not cover efficacy data or safety data not pertinent to the safety of the purchased product. These regulations are final and apply to all registrations issued by the Agency, conditional or otherwise. Thus, we believe the simplified procedures have been put in place as required.

We have always acknowledged that the registration program will take time and significant resources to complete for all pesticides. However, simplicity is not the same as brevity. The simplicity of the program lies in its focus on active ingredients and on its focus on decisionmaking which applies to broad use patterns of those chemicals rather than only to individual products.

Since we want the program to work well, we have spent considerable time planning it—to be truthful, more time than we had expected. We believe this time spent will pay off in a smoother running program.

In the meantime, if the actual reregistration of products does not occur immediately we see no harm resulting to the pesticide industry. Already registered products remain registered. New products similar to or with new uses of existing products are permitted to enter the market under the conditional registration program.

In addition, for many registrants this time until reregistration will provide them the opportunity to develop information needed to satisfy current registration requirements which has never before been developed. In fact, it is chiefly the public which has to bear the costs of this interim period until reregistration is accomplished—costs in terms of more products of unknown safety staying on the market or entering the market under the conditional registration program. However, we recognize that it is in everyone's interest to find ways to shorten the time it will take to develop standards for the 500 to 600 pesticide chemicals if this can be done without sacrificing the quality of the scientific review and the decisionmaking process.

In fact, one of the reasons for publishing an advanced notice of proposed rulemaking for registration standards was to solicit suggestions for improving this program. To this end we are considering various options for reducing the time it will take to develop an individual standard.

Mr. Chairman, there were other items and I could go on if you wish, but I think those were three of the major items that came up in the prior hearings. I am prepared to continue, if you desire, or to answer questions.

MR. DE LA GARZA. Without objection, your prepared statement will be placed in the record.

Are there any questions? Mr. Brown?

MR. BROWN. I have no questions.

MR. DE LA GARZA. Mr. Wampler?

MR. WAMPLER. I have no questions.

MR. DE LA GARZA. I have one. One of the witnesses this morning in his presentation submitted an addendum wherein he makes a proposal on the cite-all that rather than the registrant having to contact all of

the people who may or may not be interested, he suggests rather that section 3(c) (1) (D) (1) and section 3(c) (1) (D) (2)—let me read you the first one:

* * * adding the language "For the purpose of this paragraph the Administrator shall publish registration applications in the Federal Register disclosing the active ingredients contained in the product for which registration is sought, and such publication shall be legal notice to the original data submitter who shall verify his status as original data submitter or waive his rights to requirement of written permission under this subsection."

Were you acquainted with that proposal?

Mr. JELLINEK. I was not personally. Let me ask Mr. Johnson whether he was familiar with it at all.

Mr. JOHNSON. No; I had heard about the proposal although I have not seen the language itself. What we are doing in the current procedures that we are using is to follow the language of the statute as to who needs to notify of the use of data.

In the past we have used the Federal Register procedures. This was prior to the 1978 amendments. We were criticized and I believe had one court suit which went unfavorably to us on the old 2(c) method of notification wherein in fact we did publish in the Federal Register applications for registration and the active ingredient involved, I believe, and let the manufacturers who had previously submitted data for those uses read the Federal Register and attempt to contact the people they thought were using their data.

That was discarded in the 1978 amendments as being not adequate form of notification. Instead, there was substituted the requirement on the person who wished to use the information to actually notify the person whose information he might be using.

The other objection that came to the publication in the Federal Register was that these were put out before such time as the manufacturer actually received registration and it might tend to tip off marketing plans in advance fairly broadly and widely through such advertising.

I think I can say that we are open to any form of notification that generally meets the needs of the industry and we are not wedded to any particular method. If the industry feels that notification in the Federal Register is adequate and appropriate notice, I think on preliminary thought, we could probably abide by that kind of a notice process.

Mr. DE LA GARZA. Therefore, your position is that if within the scope of the statute or by amendment of the statute we can work out something—given we have tried something else for some time—that would be more amenable to simplicity, you would have no objection. Is that correct?

Mr. JOHNSON. That is correct. I think the only kind of process that the Agency might have objections to is one in which we undertook the burden ourselves of identifying each manufacturer who might have submitted data and took on ourselves the burden of advising him on an individual basis.

Mr. DE LA GARZA. That is quite understandable and agreeable. Some that I have spoken to in the industry do not want you to have to go through that and they do not want to go through it themselves but want a more simplified procedure wherein you do not have to cite half the people in the United States in order to protect three or four.

I think possibly that we can work at arriving at something, now that what we have has been tried. We would need your cooperation to see that whatever seems feasible can be implemented by you.

Mr. JELLINEK. We would be willing, Mr. Chairman, to work with members or staff of the committee to explore this and/or other options for dealing with the cite-all problem.

Mr. DE LA GARZA. If the other members do not have any questions and you have nothing further to add, I think probably we can allow you to sit back—

Mr. WAMPLER. Mr. Chairman, I do have some questions. I simply wanted to defer them until Mr. Jellinek had completed his testimony. It is another subject matter that we could delve into.

Mr. DE LA GARZA. Why don't we take a short recess to cast our votes? We will be back as promptly as we can.

[Recess taken.]

Mr. DE LA GARZA. Thank you very much for bearing with us.

At this point I do not know who had the floor, Mr. Jellinek or Mr. Wampler.

Mr. Wampler?

Mr. WAMPLER. Thank you, Mr. Chairman.

Mr. Chairman, I am sorry that I was unable to be here this morning. I had a longstanding commitment to deliver a few remarks in my district and as a result I was a bit late arriving this morning.

For the past 5 years the Committee on Agriculture has limited the authorization of funds to the Environmental Protection Agency to administer FIFRA to 1 year. In our full committee report dated September 19, 1975, it was stated:

The committee has limited the extension of the authorization to 1 year rather than the 2-year period originally sought by EPA to give it an opportunity to continue to exercise effective oversight activities over its operations, particularly in view of the controversies that have been generated in many of its activities.

Mr. Chairman, I will not deny that the administration of FIFRA has improved during these past 5 years. It has improved. However, Mr. Chairman, there is still, I think, a vast need for improvement and it is with this thought in mind that I address the following questions to Mr. Jellinek or other witnesses from EPA.

First, on or about March 1, 1979, members of your Agency came to this committee and informed us in a briefing that you were suspending the use of 2,4,5-T on powerline rights-of-way, in pastures, and in forest lands on an emergency basis. Your Deputy Administrator, Barbara Blum, summed up the Agency's reasons for the suspension, saying the emergency was justified by the imminence of spring spraying and "the potential for significant human exposure"—which your Agency estimated at 4 million who could be exposed from those uses—"the warning signals from the Alsea study, a preponderance of strong animal test data, and the low short-term economic impact compelled this unusual emergency, decision."

What I would like to ask you is this. Is this a fair statement of your reasons for halting the use of the herbicide 2,4,5-T?

Mr. JELLINEK. It is.

Mr. WAMPLER. Other than for the reason that the FIFRA does not require you to seek the advice of your scientific advisory panel when you took your action to suspend 2,4,5-T on an emergency basis, you

are required to seek their advice in all other actions to suspend, reclassify, or cancel a pesticide or its labeling.

Why did you not seek the advice of your scientific advisory panel before issuing your order on 2,4,5-T? You had that authority, did you not?

Mr. JELLINEK. We did, Mr. Wampler, seek the review of a member of our scientific advisory panel—as a matter of fact, the only epidemiologist on that panel, Dr. John Davies—who did review the critical study at the time, which was the Alsea II study released on February 28.

Mr. WAMPLER. All right. Did EPA conduct any independent scientific peer review of the Alsea study before it issued its emergency order to suspend the uses of 2,4,5-T on forests, or rights-of-way, and pastures?

Mr. JELLINEK. Other than Dr. Davies, who was the only scientific peer representative of the 10 to 12 that we contacted who was able to review the study in the short period of time we had available, we did not seek review independent of EPA.

We did, however, ask that the study be reviewed by scientists within EPA who were not associated with the study.

Mr. WAMPLER. In other words, you did have a systematic in-house review of the Alsea study.

Mr. JELLINEK. Yes, sir.

Mr. WAMPLER. In retrospect, do you think EPA's review of the Alsea study was adequate and could it have been performed by the scientific advisory panel, other than what you have already indicated that Dr. Davies performed?

Mr. JELLINEK. We think it was adequate to the occasion. We would have liked to have other individuals review the study prior to our decision, but they simply were not available.

We did not think that under the conditions that normally prevail under our procedures and under the Advisory Committee Act that it would be possible to conduct a normal scientific advisory panel hearing in the time that we had available to make a decision.

Mr. WAMPLER. Then, is it your opinion that FIFRA does not require you to take scientific issues that arise during decisionmaking in a suspension or cancellation proceeding to the scientific advisory panel for an opinion to clarify the scientific issues?

Mr. JELLINEK. It does not require us to take those issues or the suspension decisions to them but it does require us to take proposed cancellation decisions to them—

Mr. WAMPLER. Are you aware, Mr. Jellinek, that a General Accounting Office investigation is underway concerning the scientific validity of the Alsea II study, the appropriateness of your Agency's response to it, and the adequacy of existing mechanisms and procedures within EPA for properly evaluating and reviewing such studies and the extent to which you followed such procedures in this case? I am speaking now of 2,4,5-T.

Mr. JELLINEK. Mr. Wampler, as I am familiar with the GAO study, it would do the latter of the items that you mentioned. I did not understand that the GAO study was involved in the scientific validity of the Alsea study as much as it was in EPA's procedures for reviewing the scientific validity of it.

Mr. WAMPLER. Mr. Chairman, there is a representative here today of the General Accounting Office at the request of myself and Mr. Grassley. I think he is prepared to discuss their findings today on the Alsea study and other matters that we asked them to investigate and study.

I would like them to present their findings. On the basis of what I believe their findings are, I think I would be compelled to introduce an amendment to FIFRA based on their representations to me.

I do not want to prolong the hearing, but I think this is very germane to what we are doing and is an important part of our oversight function.

Mr. DE LA GARZA. Do you have any further questions?

Mr. WAMPLER. Not at this point in time; I do not.

Mr. DE LA GARZA. Mr. Brown?

Mr. BROWN. I do not have any other questions.

Mr. DE LA GARZA. Thank you very much. We appreciate your being here and your cooperation. I would suggest that you remain. We do not want to involve ourselves in an adversary capacity between two agencies, but I think it would be well for you to hear.

Mr. JELLINEK. I would be happy to stay, Mr. Chairman.

[The prepared statement of Mr. Jellinek follows:]

STATEMENT OF
HONORABLE STEVEN D. JELLINEK
ASSISTANT ADMINISTRATOR
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
ENVIRONMENTAL PROTECTION AGENCY

Good morning, Mr. Chairman and Members of the Subcommittee. Mr. Costle has had the pleasure of describing for you our progress in implementing the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Your staff has asked me to respond today to all the issues raised by the pesticide producing industry, the commercial pesticide applicators, and the agricultural community on April 15.

Since the issues raised at that time were numerous, I will address each of them briefly now and will be glad to answer any additional questions you may have at the close of my statement.

Cite-All

Spokesmen for the National Agricultural Chemical Association (NACA) and the Chemical Specialties Manufacturers Association (CSMA), in their testimony before you last month, took issue with the Agency's regulations issued in May 1979. These regulations in some cases require applicants for registration to offer to pay compensation for all the data that is relevant to the safety of an active ingredient of a pesticide product.

Our reasons for issuing these regulations are detailed in a 10-page letter to Senator Stewart, Chairman de la Garza's counterpart subcommittee chairman, dated February 11, 1980, which was made available some time ago to the Committee staff. A copy of that letter is attached to my prepared testimony, for the convenience of the subcommittee members.

As we indicate in that letter, in 1977-78 the Agency made clear to Congress our intent to review all relevant data in preparing the registration standards which we will use as the principal basis for unconditional registrations under §3(c)(5) in the future. We also note that FIFRA §3(c)(7)

expressly requires conditional registration applicants to rely, for data compensation purposes, on the same data that would be required for a §3(c)(5) registration.

NACA has indicated they will propose a system under which (1) an applicant would tell us which data he wanted us to consider "in support of" his application, and (2) we could look at whatever other data we felt necessary "so long as [the other data] are not used [by EPA] to affirmatively support" the application. This proposal is the same one that was advanced by NACA to us last summer. At that time, we told them that their approach had two fundamental flaws that precluded its adoption:

-----The NACA approach would not work in cases where we do consider all relevant data before deciding a product could be registered or reregistered (i.e., when we develop a registration standard), because, as the courts have noted, our scientists can't pretend to "forget" part of the data base for the convenience of applicants, and also because the whole reason for using a generic approach to registration is to get away from the same inefficient, duplicative review of portions of the data base that the NACA approach would require.

-----The NACA approach would not work in cases where we do not consider all relevant data before deciding a product can be registered [i.e., all the conditional registrations now being issued under §3(c)(7)(A) and (B)] for the simple reason that under the NACA approach, EPA would have to review all the data the applicant puts before us, on an ad hoc basis, for the sole purpose of deciding whether he had submitted enough data to avoid a claim by some other data owner that the latter's rights had been violated. Conditional registration of me-too products, and of new uses for old products, expressly contemplates that we will not review data on existing

uses. The idea is that we can use our resources better in the development of registration standards and other tasks, and should not hold up marketing of me-too products or new uses pending ad hoc reviews of data on existing uses.

A resolution of the cite-all issues in a fashion that would allow conditional registrations to be issued as Congress intended, and would allow us to adopt the efficient registration-standard approach to unconditional registration that we believe Congress endorsed in 1978, is outlined in the letter to Senator Stewart at page 8. We really do not have a preference on the question of whether applicants compensate data submitters for all, some, or none of the relevant data. So long as EPA is not precluded from attaining an efficient program for evaluating pesticides and issuing registrations as Congress intends, and so long as we can avoid yet another round of litigation commenced by individual firms, whatever the industry as a whole can agree upon about the extent of data compensation will be acceptable to us.

TRADE SECRETS

NACA is also concerned that the FIFRA authorizes disclosure of proprietary data which the pesticide producing industry considers to be trade secret. Disclosure of such data, NACA argues, "destroys valuable private property" and permits unfair and injurious competition within the pesticide industry.

When Mr. Costle appeared before this Subcommittee in 1977, one of the most important and controversial issues he addressed was that of trade secrets. There are two basic issues: 1) what data may be used by any pesticide producer to support product registration, and 2) what data should be accessible to the public.

EPA's long-held position which Congress affirmed in enacting the 1978 amendments, is that information about pesticide health effects should be available to the public. We should withhold from public scrutiny a narrowly limited

class of information, primarily manufacturing and quality control data and confidential formulas. The mandatory data licensing scheme created by §3(c)(1)(D) substitutes one system of protection for data (compensation and exclusive use) for that which the industry has always preferred (secrecy). At the same time the Act's carefully balanced data scheme takes account societal goals other than protection of proprietary interest. The compromise which yielded the current law took account of desirability of promoting the sharing of data development costs within the producing industry, and the value to farmers and consumers of encouraging healthy competition and access to the marketplace for firms who do not develop their own data. The law also provides through the exclusive use provision for special protection of data during the early years of a chemical's life, rewarding innovation and permitting rapid recovery of investment costs.

We continue to believe that public access to the test data upon which the Agency bases its decisions is vitally important. It is the public which must bear the costs of our decisions. Public understanding of the decision-making process and its complexities is crucial to public acceptance of the risk/benefit approach which underlies the regulation of pesticides. Moreover, public involvement in the regulatory process can improve the quality of our decisions.

FIFRA was amended in accordance with industry wishes in 1978 to provide for protection against disclosure of these test data to foreign competitors of the data submitter (including domestic firms who trade in overseas markets) or their agents. The Agency has implemented this provision in its interim procedures on handling trade secret information.

It is more than a year and a half since Congress affirmed the need for an effective data licensing program and the right of public access to test data. In that time we have seen no evidence that the pesticide producing industry is failing or suffering from unscrupulous competition resulting

from the new definition of trade secrets. The major producers flourish. The latest confirmation of this fact appears in a March 1980 report developed under contract to Congress' own Office of Technology Assessment, which summarizes the economic state of health of the major producers.

"Pesticide manufacturing is the most intensely regulated sector of the chemical industry, with the exception of drugs. But R&D investment in pesticides has increased significantly, the increase in the number of new patents obtained for pesticides in recent years is greater than for any other part of the chemical industry, sales of pesticides have soared, and at least for some companies, pesticides sales bring in higher profits than sales of other types of chemicals."

The report goes on to state "the structure of the chemical industry is quite concentrated...", a factor Congress considered in fashioning a compromise which would not only provide incentives for innovation, but would also preserve opportunities for competition.

No party involved in the lengthy legislative process culminating in the 1978 amendments, including those who now assert this argument in court, testified then that disclosure and use of hazards data, (as was contemplated, in some form, in every bill before the Committees) would violate the Fifth Amendment as an uncompensated "taking" of property for a private purpose. In fact, everyone involved appeared to find the final, clarified confidentiality, compensation, and exclusive use provisions an acceptable, workable compromise which would end the litigation then frustrating the registration process. Thus we are frankly appalled that some 18 major pesticide producers are now challenging the FIFRA amendments on various constitutional grounds and are seeking to enjoin our implementation of key provisions of the Act. One company has even asserted that FIFRA violates the prohibition against involuntary servitude. In one case now on appeal, a preliminary injunction has been issued, preventing use of plaintiffs' data until the litigation is resolved. Two other companies have resisted our efforts to have the courts vacate injunctions issued under the prior statute. In the

short run these injunctions have caused a certain disruption and inefficiency in the conditional registration process; most denials of conditional registration in fact result from them. While we are confident that the constitutionality of the statute will be upheld, the litigation, if resolved in favor of the plaintiffs, would seriously undermine not only conditional registration but also reregistration through the registration standards approach. The registration standards approach assumes that the Agency can use all scientifically relevant data in its decision-making.

The current litigation demonstrates a disregard for the legislative process (which plaintiffs allege resulted in provisions which are "without a rational basis") as an effective mechanism for resolving potential disputes in a non-adversarial forum and at relatively less expense to the public. In the long run, such litigation could not only disrupt a regulatory program which is now working but also could destroy public confidence in its government's ability to provide adequate public health protection.

REGISTRATION STANDARDS

Both NACA and CSMA assert EPA has failed to implement the "simplified procedures for registration" required by the amended FIFRA, §§3(c)(2)(C) and (D) since the registration standards program is not yet fully underway nor will it be complete for at least 10-15 years.

Specifically, §§3(c)(2)(C) and (D) exempt any applicant for registration of an end-use product from the compensation requirement imposed by §3(c)(1)(D) for data which pertain to the safety of the basic active ingredient (already registered by EPA) which the applicant purchases from another producer and uses in formulating his product.

Of course, §3(c)(2)(D) was effective upon amendment, and we have conducted our program accordingly. Data requirements for registration have been set in accordance with §3(c)(2)(D).

Registrants of end-use products have not been required to perform chronic or subchronic hazard evaluations for end-use products formulated from registered manufacturing-use products.

Moreover, the Agency has also prescribed the required simplified procedures for registration in the interim final regulations governing conditional registration and compensation for use of data published May 11, 1979, seven and one-half months after enactment of the amendments. Section 162.9-7 of the interim final compensation regulations specifically addresses this exemption: 162.9-7(a) states the terms of the exemption under FIFRA, §3(c)(2)(D); 162.9-7(b) defines data pertinent to the safety of a purchased product; 162.9-7(c) defines the term "end-use product"; and 162.9-7(d) clarifies that the §3(c)(2)(D) exemption does not cover efficacy data, or safety data not pertinent to the safety of the purchased product. These regulations are final, and apply to all registrations issued by the Agency, conditional or otherwise. Thus, we believe the simplified procedures have been put in place, as required.

We have always acknowledged that the reregistration program will take time and significant resources to complete for all pesticides. However, simplicity is not the same as brevity. The simplicity of the program lies in its focus on active ingredients, and on decision-making which applies to broad use patterns of those chemicals rather than only to individual products.

Since we want the program to work well, we have spent considerable time planning it (to be truthful more than we had expected). We believe this time spent will pay off in a smoother running program. In the meantime, if the actual reregistration of products does not occur immediately, we see no harm resulting to the pesticide industry. Already registered products remain registered. New products similar to, or with new uses of, existing products are permitted to enter the market under the conditional registration program. In addition,

for many registrants this time until reregistration will provide them the opportunity to develop information needed to satisfy current registration requirements which has never before been developed. In fact, it is chiefly the public which has to bear the costs of this interim period until reregistration is accomplished - costs in terms of more products of unknown safety staying on the market, or entering the market under the conditional registration program.

However, we recognize that it is in the everyone's interest to find ways to shorten the time it will take to develop standards for the 500-600 pesticide chemicals, if this can be done without sacrificing the quality of the scientific review and the decision-making process. In fact, one of the reasons for publishing an Advanced Notice of Proposed Rulemaking for registration standards was to solicit suggestions for improving this program. To this end we are considering various options for reducing the time it will take to develop an individual standard.

STATE REGISTRATION REQUIREMENTS

Both NACA and CSMA believe that State pesticide registration programs such as that adopted by California are inconsistent with federal registration standards and may undermine the national pesticide regulatory program. On February 1, 1980, NACA, CSMA, and a number of individual companies filed suit against California. They seek to enjoin and have declared unconstitutional certain aspects of California's pesticide regulatory program. There are five basic issues involved in this litigation which I will discuss briefly.

1) State Registration. California law requires federally-registered pesticides to be also registered under state law if they are to be sold or used in California. NACA and CSMA claim that Congress prohibited state registration of federally-registered pesticides in amending the FIFRA in 1972, and that California should therefore be enjoined from enforcing its registration requirement.

The Agency has decided to file in that case a friend-of-the-court brief in support of the state of California's position that federal law does not preempt state registration systems. It is our position that the Congress looked extensively at the question of state authority to register pesticides in 1972, and resolved this issue in favor of the states.

The legislative history of the 1972 amendments consistently and clearly shows Congress intended federal and state registration programs to exist, with federal registration requirements to serve as a national "floor," and that the legislative history of the 1978 amendments does not change this. The Agency has consistently, over the last 8 years, maintained that a State should and does have the right to impose registration requirements for federally-registered products. Accordingly, we find the industry's allegations in this regard without merit.

2) Labeling. NACA and CSMA also claim that California has imposed different labeling requirements from those imposed by EPA under FIFRA, in violation of FIFRA §24(b). The prohibition in §24(b) on additional labeling is clear; it remains to be discovered whether or not California is violating this prohibition.

3) Permits Issued by County Commissioners. California law requires any person who plans to apply any restricted use pesticide for any agricultural use to first obtain a permit from a County Commissioner. NACA and the other plaintiffs claim this requirement violates Congressional intent and should be set aside, citing federal supremacy doctrines. The outcome of this contention will depend upon 1) the facts which may be developed concerning the authority under which County Commissioners act in issuing permits, and 2) careful application of complex doctrines of statutory construction and constitutional law.

4) State Residue Tolerances. California law permits the state to set tolerances for pesticides on crops at a lower level than those set under the Federal Food, Drug, and Cosmetic Act (FFDCA). NACA and CSMA both claim this California law

violates federal supremacy. There is no simple, clear cut answer to this issue. It is of concern to EPA since application rates on FIFRA-required labeling are often set in conjunction with tolerance levels. There is an obvious concern that farmers should not be placed in a situation of unknowingly violating state tolerance requirements by following federally-approved labels. Since FDA enforces tolerance levels, their views are obviously important and we have already contacted them to seek their comments.

5) Use and Disclosure of Data. NACA and CSMA claim that California's use and disclosure provisions constitute an unlawful taking of property in violation of the fourteenth Amendment. The issues are similar to those in the litigation now challenging the constitutionality of the 1978 FIFRA use and disclosure provisions. We believe the argument is without merit.

In sum, the Agency believes that under the FIFRA regulatory scheme many states, and particularly California, perform important and useful roles in the regulation of pesticides. State registration programs can complement the federal registration program, both by focusing on issues that are relatively more important at the state level and by bringing new ideas and fresh approaches to the attention of EPA.

REPORTING OF ADDITIONAL DATA

Both NACA and CSMA have stated that EPA has interpreted the reporting requirements of §6(a)(2) in a manner which exceeds the actual requirements imposed by that section of the Act.

FIFRA §6(a)(2) requires registrants to report to EPA any previously-unreported "factual" information concerning a pesticide's potentially unreasonable adverse effects. As NACA has indicated, EPA revoked its 1975 regulations implementing the §6(a)(2) reporting requirements and subsequently published an interpretation in August 1978 stating which kinds of information need not be reported. Following negotiations from which industry representatives withdrew,

the Agency published in July 1979 a policy statement identifying the types of information which, although subject to the reporting requirements, the Agency does not currently consider necessary in order to properly discharge its statutory responsibilities. Both the interpretation and the policy statement are attached to my statement for your reference.

A recent decision by the U.S. District Court for the District of Columbia has resolved most issues concerning proper interpretation of §6(a)(2) in the Agency's favor. The court essentially interprets §6(a)(2) to require submission of an item of information to EPA if:

- 1) The registrant possesses the information and it pertains to one of its registered products; and
- 2) The information, if true, would be relevant to an Agency decision regarding the risks and benefits of the pesticide, that is whether it is registrable or what the terms and conditions of registration should be.

If such information has been previously submitted to the Agency in writing or if it has been accurately presented or summarized in a previous submission, that information need not be submitted again.

The August 1979 policy statement further elaborates what information need not be reported because the Agency considers it to be previously reported. This includes scientific publications abstracted in several standard, well-known abstracts if the active ingredient or product is clearly identified; publications of various federal agencies; or documents in EPA files. In addition, the policy statement identifies types of toxicological, epidemiological, efficacy studies, and incident reports which the Agency considers essentially duplicative of information already in its possession and which we will not hold registrants accountable for submitting, although they are otherwise reportable under §6(a)(2). Thus NACA and CSMA are in error when their spokesmen suggest EPA

will hold registrants responsible for submitting all information --even trivial and duplicative information--on a pesticide. We do agree with NACA that so far as it is possible, consistent with the different provisions of the TSCA and the FIFRA, EPA should have a harmonious position on the reporting of data. We will work to ensure this is so. In addition should NACA, CSMA or other industry representatives wish to resume discussion with EPA concerning the provisions of §6(a)(2), we are ready at any time.

SCIENCE ASSESSMENT

Several earlier witnesses, including NACA and the National Pest Control Association (NPCA), have raised the general issue of the quality of EPA's scientific reviews and whether EPA has made sufficient use of the Scientific Advisory Panel (SAP) review mechanism.

As you know, the SAP was created by Congress in 1975 specically to review the quality of our scientific reviews which form the bases for regulatory actions. As NACA itself has stated in testimony, EPA has been responsive to the comments and recommendations of the Panel. In fact, the Agency has reviewed its track record on its referral to SAP of pesticide chemicals under Agency review, as required by the FIFRA, and our response to SAP recommendations. We have referred proposed actions on 13 different chemicals as well as informal and formal presentations on proposed or final regulations including subparts of the registration Guidelines and the classification of pesticides for restricted use. In general, the SAP has agreed with our evaluation of the risks to health and the environment posed by the pesticides under consideration, and has supported our overall proposed course of regulatory action. The SAP has of course questioned particular aspects of each proposed decision, and the Agency has in some cases modified its decision and in others remained with its original position. (On occasion the SAP has also exeeded its statutory mandate by reviewing agency disposition of product registrations.)

There have been only two cases in which the Agency has exercised the waiver provisions for SAP review provided in the statute by the Seiberling amendment adopted with the Committee's consent on the House floor in 1975. In these cases, the action was taken on an emergency basis to protect public health -- the only circumstances in which the statute permits a waiver. In one of these, the herbicides 2,4,5-T and silvex, the Agency faced the imminent onset of large scale spray operations just days from the point at which disturbing new evidence was developed and validated. Eventual review of much toxicology data considered in reaching our regulatory decision led the SAP to agree with several key EPA findings, although their advice concerning the appropriate response was frankly puzzling. The Panel in effect recommended that we not hold information gathering hearings along with hearings already underway on the suspended uses. We rejected this recommendation because it made no sense to us not to resolve all questions involving these herbicides in one hearing.

The other case involved the fumigant DBCP. Some uses were suspended in 1977 on an emergency basis without prior SAP review. In 1979 new information led us to propose a hearing under §6(b)(2) in which the significance of that data could be evaluated. The SAP's review of this data prompted them to recommend that the previously unsuspended uses be halted even while the hearings were underway.

In summary, sometimes we do disagree with the SAP and find that a more or less stringent measure than the one they support is most appropriate, considering the benefits as well as the risks of the pesticide uses in question. Such differences are not surprising however, considering that risk assessment is not an exact science, but rather a process which, while scientifically supported and necessary for regulatory action, is still full of uncertainties. These differences are usually administrative differences rather than scientific differences. We continue to respect and value the SAP's

viewpoints and consider the Panel as an important contributor to balanced decision-making.

Thus, the Panel's response indicates the Agency's scientific reviews are well done and sound. I should point out that we also receive scientific advice from the Administrator's Science Advisory Board on certain issues as well as the SAP. Frankly, I believe that those who claim Agency decisions are based on poor science are actually mistaking lack of scientific consensus for poor science. Scientific consensus is, of course, a praiseworthy goal. However, certain scientific issues, such as degree of risk posed and variation in species response, may well be controversial for lack of definitive scientific knowledge and evidence.

To the extent that scientists can reach a consensus on a particular scientific issue, EPA's responsibility to protect public health from unreasonable adverse effects of toxic chemicals is made somewhat easier. Good science - a reliable assessment of the kinds and degree of harm posed by a toxic chemical - is a primary objective element of the risk/benefit balancing process the Agency must follow in reaching what is ultimately a subjective regulatory decision. But though scientific certainty is always desirable, our responsibility to the public nevertheless requires us to trade off a degree of such certainty for timeliness in making decisions. As regulators we must decide on the weight of contemporaneous evidence, and cannot have as our objective the resolution of each and every scientific issue related to our decisions. Making no decision, or postponing a decision for the sake of complete certainty, is itself a decision to permit continued use of substances with possible serious adverse effects.

While our decisions must be firmly based on the best assessment of risks and benefits, the final decision is, by its very nature, necessarily a subjective one, dependent on the relative values the decision-maker ascribes to the human health, environmental, economic, and social factors to be

balanced. Thus EPA's decisions will not always, and may never, please everyone. Reasonable people can (and often do) differ on the environmental decision which ought to result from a set of facts.

RPAR

The American Farm Bureau Federation (AFBF) has expressed concern that the length of time it takes the Agency to complete an RPAR review has caused farmers to experience problems, particularly to decrease their use of RPAR'd pesticides such as toxaphene. The AFBF is further concerned that EPA chooses benefits data selectively, rather than relying on data which would reflect typical rather than abnormal use. Of course, this latter charge is diametrically opposed to the general conclusions of the recent National Academy of Science report on quantitative analysis in pesticide decision-making. While generally laudatory, NAS nevertheless faulted EPA for accepting benefits data based on assumptions which were more likely to result in exaggerating benefits than in under-estimating them.

Since, during the entire course of an RPAR review, a pesticide may legally be used for all previously-approved uses, I do not believe that the fact that an RPAR review is underway will deter Farm Bureau members or other users from using such a pesticide when it is needed.

I believe the AFBF has also slighted the progress which has been made in the RPAR program. After preliminary review, we decided not to issue an RPAR on four chemicals. In addition, the Agency has concluded RPAR reviews, at least to the proposed decision stage, for 12 other chemicals. Of these 12, we have proposed or actually taken final action to cancel or suspend most major uses for only 3 pesticides - DBCP, 2,4,5-T, and silvex. In these 3 cases, the regulatory process is not yet complete. With six of the 12, we decided to continue (or proposed to continue) all of the major uses, with label modifications. For the remaining 3, the number of uses

retained is about equal to those lost. This, as Mr. Costle noted, is a balanced and responsible record of decision-making.

Since the AFBF expressed concern that certain benefits data on toxaphene are being disregarded or excluded during the review process, I might also note that we are planning to issue a proposed decision on toxaphene in July this year. That proposed decision will be based in part on benefits data dating back several years, some of it to 1973. Moreover, because the decision will be only proposed, not final, there will be a period for comment and Agency review of new information received, such as 1980 growing season use data, before we issue a final decision. The AFBF and this Committee should be assured that we do seek, review and use reliable data on benefits, as well as risks, in reaching RPAR decisions - that is, in fact, one of the major contributing factors to the time it takes to complete RPAR's. We rely heavily on USDA to help us compile the most accurate benefits data so that our decisions are based on the real world situation.

RECERTIFICATION

Among the issues raised by the NPCA was that of recertification of certified commercial applicators in Colorado and Nebraska where federal certification programs have been set up. NPCA has testified that despite EPA's official position that recertification may be accomplished by testing or training (expressed in the August 1979 "Statement of Policy on the Recertification of Training of Commercial Applicators in Colorado and Nebraska under the FIFRA, as Amended"), in fact EPA has not made provision for recertification by training. NPCA says that PCO's are thus required to take a written test whereas recertification by training would ensure adequate continuing education among certified commercial applicators.

Since over 90% of the commercial applicators in Colorado and Nebraska have already been recertified by training rather than by testing, I cannot understand how the NPCA members have found EPA's recertification policy to be "punitive,

unnecessary, and contrary to the best interests of cooperative support from the pest control operators...." Rather, I suspect the NPCA has not gathered up-to-date information on what is actually happening in the field.

When EPA published the Policy Statement in August 1979, we did not have the resources to conduct our own training program. The Statement specifically acknowledged this situation and pointed out that the availability of training would depend upon the willingness and capability of public or private organizations to develop recertification training programs approved by EPA. The Cooperative Extension Service and Purdue University have since developed such programs, Purdue's program being limited to rights-of-way maintenance and, as I have said, the overwhelming majority of commercial applicators have been recertified by training. I do not believe there is a problem here.

GRASSLEY-THORNTON AMENDMENT

Earlier testimony from industry alleged that EPA has not heeded the so-called Grassley-Thornton amendment adopted in 1978. That amendment says that the EPA Administrator may not initiate an "interim administrative review process" (in other words, an RPAR notice) unless the review is based on "a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or the environment."

We are mystified by the charge that we have "ignored" the amendment. Since no specifics were offered in the earlier testimony, I can only respond by explaining what we have done in a general way to comply with the amendment.

First, we published (on February 14, 1979) in the Federal Register a definition of "validated test" and "other substantial evidence" in accordance with the law and in harmony with the language suggested in the House report. Secondly, we have sent letters as a matter of routine to all registrants explaining our concerns about a chemical well before an RPAR notice is

issued. This was our policy even prior to the 1978 amendments. Third, we had extensive correspondence with the registrants of EPN -- the only chemical we have RPAR'ed since the amendments were passed, prior to the issuance of the RPAR notice. After considering the registrants' comments, we still believed that we had "validated tests" on the potential risks of EPN which raised "prudent concerns" about the health effects of the pesticide. These are well documented in the RPAR notice.

Although EPN is the only RPAR we have issued since the 1978 amendments, we have on numerous occasions afforded registrants ample opportunity to respond to Agency concerns about data on many specific pesticides. These communications have certainly been within the spirit of the Grassley-Thornton amendment. What I think the industry must understand is that the law does not entitle registrants to carry on protracted, secret negotiations from which the public is excluded. The amendment ensures that EPA will not RPAR a chemical on a whim; but it does not eliminate participation in EPA's decision-making by private citizens, members of academia, and agricultural and environmental (or other interest) groups when a valid health concern is raised.

DISTRICT COURT VS. COURT OF APPEALS

Earlier testimony alleges that EPA tries to have as many cases as possible heard in the Court of Appeals rather than District Court. The role of the Court of Appeals was specifically addressed in the Congressional deliberations in both 1975 and 1977-78. NACA suggested in 1977 that there was an ambiguity in section 16 about which court should review Agency decisions. The provision was expressly considered and not adopted by either House. Our comment at that time (at page 112 of Senate Report 95-334) was that "NACA's suggestion here amounts to an attempt to reopen an issue which was resolved against them in 1975 and with which we have had no further experience in the interim that would justify reconsideration."

In point of fact, recent significant licensing actions under FIFRA, including the suspension of 2,4,5-T and EPA's approval of an exemption for limited uses of Ferriamicide to combat fire ants in the South, have been litigated in District Courts. Likewise, NACA's challenge to our interpretation of FIFRA's requirement to report adverse effects data was decided by a District Court. And the numerous suits by NACA and its members to set aside the major provisions of Congress' 1978 actions have all originated in District Courts.

We continue to believe that Agency actions for which there is a reviewable record (including the "record" of cancellation or "suspension trials" amassed over months or even years) are most appropriately referred to a Court of Appeals.

In view of the fact that FIFRA clearly establishes the bases for review in Appeals and District Courts, and that NACA cites no instance in which EPA has acted contrary to section 16, the accusation that the Agency "is thwarting" District Court review is absurd.

DIFFERENCE BETWEEN AGRICULTURAL AND NON-AGRICULTURAL PRODUCTS

The CSMA argued that EPA is still not taking the differences between agricultural and non-agricultural products into account in regulating household products. They cite as an example the required label statements for sodium hypochlorite products, and EPA's draft guidelines for worker protection.

We certainly do take both the use pattern and the toxicity of a pesticide into account when developing requirements for data or labeling. There are many cases in which we do not need as extensive a data base for house and garden products as we do for a major crop pesticide. But household products are not always more "safe" than agricultural products. Obviously, high exposure to a highly toxic household product can be more potentially hazardous to an individual than less exposure to a less toxic agricultural product. It all depends on the anticipated exposure and the anticipated toxicity, as formulated, of individual pesticides.

Sodium hypochlorite products bear the signal word "Danger" because they are extremely corrosive to the eyes and skin. If they were also highly toxic, they would bear not only the word, "Danger," but also the skull and crossbones. We are concerned about the potential effects of accidental contact with the product, as used in non-agricultural settings, on the eyes and skin. That is why we insist that labels bear instructions for protection of the eyes and hands.

The draft worker protection guidelines do not anticipate that all household products will have reentry intervals. On page 16 and 17 of the draft we talk about the differences in applicability of the guidelines for agricultural and non-agricultural uses. On page 17 we describe where we would most likely require reentry intervals: "...kennels, houses, warehouses, and other buildings and structures where pest problems sometimes become so intense that fairly drastic, often broadscale measures which include pesticide treatment must be taken." A good example would be fumigation of an entire building; obviously, in such a case, you need to know the time when it is safe for people or animals to reenter the building. These guidelines, I may add, have not even been proposed in the Federal Register as yet, and we are open to suggestions from CSMA on how best to deal with reentry for non-agricultural uses as appropriate.

GUIDELINES

CSMA also objected to the fact that EPA has not finalized the registration Guidelines, but uses the proposals as the basis for registration requirements. They also said the EPA did not keep the public informed on Guidelines scheduling.

First, let me say that we will issue final Guidelines this year on several important subparts -- Wildlife and Aquatic Organisms (target June 1980), Product Chemistry (July 1980), Environmental Chemistry (August 1980), and Human Hazard (September 1980). I think it is important to understand that it takes so long to develop Guidelines because

we allow for extensive public participation and thoroughly think out what requirements make most sense and are reasonable economically. Each subpart of the Guidelines is reviewed separately in 3 or 4 public meetings in addition to a 60 - 120 day comment period. All letters and comments are individually considered and recommended changes are often accepted.

We believe it is appropriate to use our proposed Guidelines pending the development of a final document, since our proposals represent the Agency's most up-to-date thinking on what data are appropriate to consider for registration purposes. But of course there are instances where chemical composition or other characteristics of a pesticide may make it more appropriate to use a testing procedure which is not described in the Guidelines in lieu of one that is. Where a scientific rationale for the change is presented by an applicant we have and we will accept the more appropriate test. But it frankly baffles me to understand how anything but additional delay, uncertainty, and confusion, not to mention the potential for inequitable treatment among applicants, would result from a policy of pretending that the draft and proposed Guidelines do not exist and instead "negotiating" data requirements with each manufacturer for each application.

Scientific knowledge and technological procedures are always evolving, and we anticipate that the Guidelines will be continually revised over the years. The Guidelines will never really be "final" because scientific knowledge about testing techniques keeps advancing. But this does not mean that tests already completed or underway must be redone. In virtually every case, the changes will be applied only prospectively. So while we agree that final Guidelines are important and we are working toward final rulemaking on many fronts, the most important thing is for the Agency to make clear what the requirements are and to keep the public advised of all proposed changes to the way we're doing business.

As far as keeping the industry informed about our Guidelines plans, EPA publishes a regulatory calendar in the Federal Register twice a year, and this includes a schedule on Guidelines development. In addition, our Guidelines Program Manager is happy to provide schedule information to anyone who calls or makes an appointment for a personal visit. He answers about 3 such requests a day. In addition, requests for status reports at public meetings, such as SAP meetings, are always honored.

ADVISORY OPINIONS AND BUFFER ZONES

Several witnesses discussed EPA's ultra-low-volume advisory opinion, the Arizona cotton defoliant/desiccant advisory opinion, and the use of buffer zones for aerial application of pesticides. Most witnesses expressed dissatisfaction with the Agency's use of such advisory opinions.

This is an issue where emotions are particularly strong right now. On one hand, there is an increasing public concern about pesticide drift from nearby spray operations and the right of citizens to not be exposed to pesticide risks against their choice. Many citizen coalitions are demanding that their government, both at the Federal and local level, protect them from unwanted spray drift. On the other hand, the pesticide user community whose livelihood depends in one degree or another on pesticide spraying fear that the demands of private citizens will result in unreasonable regulations which will drive them out of business. Extreme positions are advocated by both sides. As in most cases, the right answer will lie somewhere in the middle.

There is a great deal of misinformation abounding on the subject of our position on aerial application. Some people believe that the petition submitted by a private environmental group and published for comment by EPA is proposed rulemaking or an endorsement by EPA. It is not. Some believe that advisory opinions, which are recommendations and clarifications of what actions will be considered "consistent" with the label, are "back door"

rulemaking. They are not. Drift from many pesticide products currently registered is frankly "inconsistent with the label" which, if strictly enforced could result in civil penalties. An Advisory Opinion explains what use practices we will consider "consistent" with the label even if drift does occur and a technical violation is committed. (We have issued two Opinions, one on ultra-low-volume application and one on cotton defoliation in Arizona in order).

This is an area we've begun to address in earnest very recently. We're thinking about ways to clarify pesticide labels, many of which are sorely out of date or vague, and about ways to approach the whole question of drift through a comprehensive rulemaking process with ample public participation. Advice from you now, or when alternative techniques are more clearly in sight, will be helpful to us, as are comments from individuals and organizations who may be affected. Of course, any regulation which may be proposed in the future would be subject to statutory review mechanisms.

Because earlier witnesses have especially cited our action in Arizona, about which we apprised you many months ago, I would like to reiterate that EPA developed a set of practices for use there with desiccants and defoliants which would reduce drift from the treated crop to adjacent homes, schools, shopping centers, and streets. We monitored practices which had been in use and found that pesticides were consistently migrating to densely populated areas, and could be detected in homes and residents themselves. Most of the products involved carried label statements prohibiting drift. But by following the equipment recommendations and other practices EPA developed, our Advisory Opinion informed applicators of the steps they could take to ensure that even if drift did occur, EPA would find that they had sprayed "consistent with the label." As far as we can tell, the Advisory Opinion worked very well last year. And I emphasize that we are talking here about attempts

to minimize drift in specific sensitive areas, that is, where population is heaviest.

This is an issue which is increasing in importance all the time. It can only become more difficult in the days and years ahead as urban and agricultural areas come closer together. One thing I am sure of and that is citizens are demanding their rights to be informed -- at the minimum -- about what chemicals they and their children are being involuntarily exposed to. And agricultural groups are demanding their rights to spray as they have always done in the past. It is an area where reasonable compromises and consideration for the other person's point of view must be advanced. I hope you will offer your good thoughts in our efforts to strike the right balance in this difficult area.

BEE PROTECTION

Testimony was also offered by the American Honey Producers Association which discusses the severe adverse impact of insecticide applications to foraging honey bees. The Association urged more emphasis on label enforcement, integrated pest management, better information in the field, research into bee protection and bee losses, and a ban of time release pesticides.

I share the Association's concern about bee protection, and agree that more should be done in many of the areas suggested in their testimony. I believe that some States, which are of course the primary enforcement agencies on label compliance, are increasingly aware of bee losses and are stepping up regulations to protect bees. What it seems to me is needed most of all at the State and local level is increased communication between applicators and beekeepers. I cannot presume to speak for USDA, but I do believe the Association's suggestions on increased information and, I would add, coordination at the Extension Service level could be helpful.

I cannot support a "ban" on all time release pesticides at this time, but I do think we and the industry can do a

better job of reviewing the effects of new microencapsulated pesticides prior to marketing. Effects on beneficial insects are becoming increasingly important in our pre-registration reviews, and we are about to go to the SAP with some proposed new Guidelines specifically on non-target insect effects in the next few months. We have also imposed additional data requirements on a primary manufacturer of microencapsulated pesticides to develop new methodologies for detecting the capsules, and have refused to register certain new uses which would be applied at bloom. In addition, there will be a pilot program under a grant to Cornell University this summer to collect information on bee losses. Data on bee losses for all States should become increasingly available through our own incident reporting system with the publication in beekeeper journals, due momentarily, of the guidelines on reporting pesticide related bee kills.

PRIMARY USE ENFORCEMENT

As you are aware, the Agency was actively engaged in a program of cooperative enforcement with States at the time the 1978 amendments were under consideration. When the amendments became law in September of 1978, thirty eight States were formally cooperating with EPA in the enforcement of pesticide laws. Since passage of the 1978 amendments, 52 States and Territories have obtained primary use enforcement responsibility.

The Agency has been working closely with State pesticide officials to implement the primary program. EPA's responsibility in this area is one of program oversight and to enforce in emergency situations or where a State response is either inappropriate or inadequate. While this may lead to some disagreements between the Agency and States, in general, we do not intend to second guess States. Our policy will be to focus already scarce Federal resources on those situations, in which public health or the environment are endangered because States are unwilling or unable to adequately respond. We will not duplicate State enforcement actions taken in response to minor violations.

Mr. Chairman, you have previously heard testimony that EPA has not been abiding by the primary use enforcement provisions of FIFRA. While there have been some inconsistencies in the application of our guidance on primacy by our regional offices, when factual examples of error on the part of EPA enforcement personnel were brought to the Agency's attention, they were corrected immediately. However, I don't want the Members to be left with the impression that these problems are either widespread or continuing. Since passage of the 1978 amendments, EPA has had numerous meetings with State pesticide regulatory personnel. Twice yearly, we meet with the entire membership of the Association of American Pesticide Control Officials. As with any major cooperative program there have been rough spots, but the manner by which primary use enforcement responsibility has been implemented has not been raised as a matter of concern by our State counterparts.

This concludes my statement. I believe I have fully addressed the issues raised in earlier testimony on April 15, but I will be glad to answer any further or new questions you may have.

Honorable Donald Stewart
Chairman, Subcommittee on
General Legislation
Committee on Agriculture,
Nutrition, and Forestry
United States Senate
Washington, D. C. 20510

FEB 11 1980

Dear Mr. Chairman:

You have requested additional information about modifications to the pesticide registration program which were accomplished by regulations issued on May 11, 1979, (44 FR 27945). Specifically, you asked that we discuss the reasons for our decision to adopt a "cite-all" requirement in those rules, under which certain kinds of applications for registration would be eligible for approval only if, for data compensation purposes, the applicant acknowledged his reliance on all data in the Agency's files which are scientifically pertinent to the product's registrability. You also requested an analysis of alternatives to the "cite-all" requirement.

The data compensation provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), and the impact of those provisions on the various registration programs authorized by FIFRA, are extraordinarily complex subjects, and my attempts to explain them in a simple, understandable way have frequently been unsuccessful. However, if you will bear with me, I will try to shed some light on these subjects for you. I will start with a discussion of certain vital features of a workable pesticide registration program, features which must be reflected in any system which is used. Next, I will summarize the relationship between the various kinds of registration programs authorized by FIFRA and the data evaluation which our Agency conducts. I will then review our presentations to Congress in 1977-78 and explain why we believe Congress endorsed our basic view of the essential characteristics of the program. I will conclude the letter with discussion of an alternative approach which is the subject of ongoing discussions between industry spokesmen and the Agency.

Vital features of a workable registration program.

For the pesticide registration program to work as Congress intended, it must, we believe, include certain basic elements. Because, as we will detail below, we believe that the Conference bill demonstrated Congress' agreement with our views about the essential elements of a workable registration program, we think that our May 11, 1979, regulations represent a proper means of implementing §3(c)(1)(D).

It is vitally important to the integrity of the program that scientific consideration of pesticide hazards and benefits not be hampered by artificial constraints on the "availability" of existing data. We know of no credible scientific reason for ignoring any portion of the scientifically relevant data base when we are making a comprehensive evaluation of the risks and benefits of a pesticide in order to decide how a pesticide may be used in the future. Moreover, it is our understanding that the various parties who are now challenging the 1978 amendments and the compensation regulations freely concede the logic of this, and agree that under the 1978 statute EPA is free to examine all scientifically relevant data in making registration and reregistration decisions.

We further believe it is vital to the pesticide registration program that we be free to conduct data validation and examination in an orderly and sensible manner, and that we not be required to alter our data review schedules on demand in response to the filing of applications for new products or amendments to old registrations containing active ingredients that have been used for many years. This is the other important component of the "generic" approach to reregistration: looking at all the data on a particular chemical at one time, issuing a registration standard, and moving on to the next chemical, all

according to a schedule which reflects sensible review priorities and allows us to make the most efficient use of our scientific personnel and other resources. Until a standard is prepared for a given active ingredient, we must be able to process me-too applications and requests for new-use approvals under the conditional registration authority. Looking only at the data needed to assess incremental risk. By abandoning the product-by-product (really application-by-application) review of data, except for that needed to assess the incremental risk of proposed uses, EPA will realize the resource savings needed to operate a rigorous reregistration effort and provide the hazard evaluation capability necessary to provide timely action on: experimental use permits, emergency exemption requests, applications to register new pesticides, applications to register new uses of previously registered pesticides, and conclusions of the review of suspect chemicals (RPAR) which have already been initiated.

It also is obviously important that any use-of-data program we implement carry out the decision, made by Congress in 1978, that all data on "old" active ingredients shall be subject to mandatory licensing. As you know, most of the large, data-submitting companies have challenged the constitutionality of the mandatory-licensing provisions of the 1978 amendments. However, the outcome of that litigation is only indirectly connected to the issue of whether the "cite-all" approach to data compensation is authorized by the language of the statute and if so whether it is the best approach to use.

Finally, we are extremely interested in finding an approach to the data compensation program which can proceed without the delays and resource drain caused by court challenges, or which at least minimizes the kinds and number of such challenges. As we explain later in this letter, the "cite-all" approach was based in large part on our assumption that since we were going to review all scientifically-relevant data, we would face immediate litigation with data submitters if we did not require all applicants to acknowledge their reliance on all scientifically relevant data.

In summary, what is important about data compensation procedures from EPA's standpoint is that (1) we must be free to use all scientifically relevant data in our decision-making, (2) we must be able to conduct data reviews in an orderly and comprehensive manner, rather than being forced to review portions of the data base for any chemical whenever a conditional registration application is received solely because of data compensation concerns of the applicant, (3) the court challenges must be held to a minimum, and (4) the Congressional decision allowing mandatory licensing must be recognized.

The relationship between registration actions and data evaluation.

As amended in 1978, FIFRA authorizes two basic types of registration: "unconditional" or "full" registration under FIFRA §3(c)(5), and "conditional" registration under FIFRA §3(c)(7). Unconditional registration requires a thorough Agency evaluation of all the risks of a pesticide's use, and an Agency determination that the benefits of use outweigh those risks. Conditional registration, on the other hand, requires evaluation only of the additional risks, if any, that registration of the new product (or new use of an old product) would pose, over and above those risks associated with the already-registered uses of products of the same type.¹

The risks posed by existing uses of registered products are to be evaluated during a process called reregistration. FIFRA §3(g) requires reregistration of all registered products to be done as promptly as is practicable. Reregistration will involve a systematic review of all the data that has been submitted concerning each pesticidally-active ingredient. If all required data do not yet exist, or if some existing studies are found to be fundamentally deficient, new studies will have

¹ Conditional registration also is authorized for products containing new active ingredients, in some cases, but that authority is not pertinent to this discussion.

to be performed, submitted, and evaluated. This evaluation will be published in a document called a "registration standard." Once all this has been done, old products can be reregistered for the uses found acceptable, and new products can be registered for those uses. These registrations and reregistrations would be unconditional in nature.

Conditional registration was authorized in 1978 as a means to allow new products which contain "old" active ingredients to be registered promptly (and to allow prompt approval of new uses of such products). These actions otherwise could not have been taken until all required data had been submitted and evaluated under the criteria for unconditional registration. Since much of the data now required for an unconditional determination never has been submitted (or, if submitted, may contain fundamental flaws), and since in any event the evaluation of all the data on all already-registered pesticides will take a considerable time (we have estimated 10 years or more may be required to complete all the evaluation), conditional registration was seen as a necessary "bridge" to avoid a near-complete shutdown of the registration process over the next several years. Since work on registration standards has just begun, almost all registrations we are issuing at this time are conditional in nature.

Basis in the 1977-78 legislative history for the "cite-all" approach.

It has been the Agency's publicly-announced intention since 1977 to reregister products by a process which involves (1) examining all the data we have which is scientifically relevant to the registrability of the products in question, and (2) preparing a "registration standard" (or "generic standard"), based on our review of all that data, which states the terms under which we are willing to reregister products containing a given active ingredient and thereafter to unconditionally register new products containing that active ingredient. Once such a standard has been published, we would approve an application for unconditional registration only if the product were found to conform to the standard. (New formulations or use patterns developed after the standard is first issued would be handled by amending the standard once the new product or use is found approvable.)

Our intention concerning the data we would review was stated plainly in comments we furnished to your Subcommittee on June 16, 1977 (printed at page 107 of S. Rep. 95-334, the Senate Committee Report on S.1678):

EPA believes that the real value of generic registration is that it will enable us to make better and broader decisions. Under the expeditious process generic approach, a standard will be built based upon all available data on a particular chemical. Applicants will then rely on the standard for registration...

... [O]ur initial decision in establishing a chemical standard will be based upon intensive analysis of the broadest range of information available... [Emphasis added.]

During the period that the 1978 amendments were being considered by the Congress, and for some time after the amendments were enacted, EPA assumed that the major data-submitting companies would take the position that if any part of an EPA decision to unconditionally register or reregister a product was based to any degree on an item of post-1969 data submitted by a particular firm, that firm would be entitled by 53(c)(1)(D) to compensation for EPA's "consideration" of that item of data. Section 3(c)(1)(D) certainly can be read that way. We had previously been sued by data submitters who had claimed that we had improperly issued me-too registrations without sufficiently protecting the rights of those data submitters. These suits argued that the me-too registrations should be cancelled. We regarded such litigation as having the potential for catastrophic disruption of the registration process, and we were thus intent on implementing the 1978 amendments in a manner which would unquestionably afford to data submitters the full degree of protection that the statute provides.

Accordingly, our approach to data compensation started from the premise that each applicant would be required to acknowledge reliance, for compensation purposes, on all the data we would consider in making unconditional registration decisions. Our intent in this regard was further clarified in a letter to Senator Leahy from EPA Administrator Costle dated January 25, 1978, which stated that under the Senate's version of §3(c)(1)(D), which we favored over the House's, the Agency:

will be able to consider all available data establishing the standard, and through the mandatory licensing provisions, all applicants will be able to rely on the pertinent data which forms the basis for that standard ... [Subsequent applicants] would be ... responsible to work out appropriate cost sharing (compensation) with previous submitters of all data...used by EPA to develop the standard ... This defines a clear, complete and unambiguous set of compensable data which is the same for each subsequent registrant until amended by new data. [Emphasis in original.]

The National Agricultural Chemicals Association (NACA), the major trade association for agricultural pesticide producers, was well aware of the Agency's proposed approach. In a March 2, 1978, letter to Senator Leahy, supporting the exclusive-use approach in H.R. 8681 and responding to Mr. Costle's January 25 letter, NACA's president set forth his organization's understanding that EPA planned to require each applicant to rely on all data that formed the basis of a standard. He noted that some firms might disagree with this approach, because an applicant might wish to "produce and rely solely on his own data ..." He conceded that such questions "are subject to administrative solution," but went on to argue for adoption of the exclusive-use approach which the Conferees ultimately rejected insofar as data on "old" active ingredients is concerned.

Although several new chemicals have been registered since enactment of PL 95-396, and plans for the first reregistrations are well underway, most of the registration actions which have taken place are conditional registrations of products containing "old" active ingredients. Since it was easy to foresee that this would be the case after the amendments were adopted, much of our concern about data compensation was related to conditional registration. The Agency was sensitive to the industry criticism that EPA had permitted an inequitable "free ride" on data under earlier versions of § 3(c)(1)(D). Therefore, our legislative proposal devised in 1977 sought to match compensation obligations for conditional registration to those that would apply to unconditional registrations. We expected that a less protective approach would prompt industry assertions that conditional registration was merely a device to permit an extended period of "free rides." Without significant opposition on this aspect of the Administration bill emerging during further hearings, it is not surprising that S. 1678, and H.R. 8681 both provided that applicants would have to rely on the same data base that would be required of applicants for unconditional registration. The Senate and House committee reports both pointed out explicitly that this requirement was inserted for data compensation purposes.² (This was only logical, since both reports also recognized that EPA would not actually review the data supporting already-registered use patterns at the time of conditional registration).³

The House bill's version of the conditional registration authority did contain an exception which related to that bill's exclusive-use provisions. In a January 25, 1978, letter to the Chief Counsel of the House Committee on Agriculture, commenting on the differences in the Senate and House bills, Edwin L. Johnson stated on behalf of the Agency:

Proposed FIFRA Section 3(c)(7) of both bills would allow conditional new-product or new-use registrations. The Senate bill would require all applicants to cite all existing data, but the House bill contains an ambiguous and potentially troublesome exception ... [Emphasis added.]

² Rep. 95-334 at pp. 20-21; H.R. Rep. 95-663 at p. 28.

³ Rep. 95-334 at pp. 20-21; H.R. Rep. 95-663 at pp. 27-28.

The exception in question was rejected by the Committee on Conference, and the Senate provision was enacted (as recommended by the joint committee staff.)

Prospects for resolution of the controversy.

A major data-producing firm may have two different (and conflicting) sets of interests concerning the use of data in pesticide registration. As a data submitter, such a firm may believe that a "me-too" applicant should be required to compensate the data submitter for the right to obtain a registration which arguably is based on the risk/benefit conclusions derived from all previous data submissions. Carried to its logical conclusion, this would suggest that a major data submitter should favor a mandatory "cite-all" approach.

On the other hand, most firms which have submitted much data to EPA also continue to actively seek new and amended registrations. In its posture as an applicant for registration, such a firm may prefer not to be required to compensate, or even negotiate with, other firms who also have submitted data. From this standpoint, such a firm may have reason to oppose the "cite-all" requirement if the firm itself has submitted a set of data which meets the minimum requirements set forth in the registration data guidelines, or if the firm has obtained permission to rely on another firm's set of satisfactory data.

From comments we have received over the last several months it appears to us that the major data-submitting firms have decided that their opposition to the "cite-all" requirement, stemming from their interests in their roles as applicants, takes precedence over any desire they might have as data submitters to obtain added benefits under a "cite-all" requirement. As we have noted, our Agency has no particular reason to insist on a mandatory cite-all approach if the procedures for data compensation can be modified in a manner providing reasonable assurance that generic registration, conditional registration, and mandatory licensing can proceed in accordance with the Congressional mandates, and if we obtain reasonable assurance that the modifications will not bring about further litigative challenges and delays.

Over the past several weeks we have been discussing with industry spokesmen a proposal for resolving the disagreements on the subject of the "cite-all" requirement, and for settling litigation which has been filed on this subject. Based on discussions concerning this proposal, we believe it may be possible to reach agreement on an approach with the following major elements:

(1) The industry would acknowledge that EPA has the right under the provisions of FIFRA to examine, at any time, whatever data we believe should be examined in making any decision about the registrability of a pesticide product, and to require further data submissions reasonably required to answer scientific questions about the risks or benefits of any product.

(2) The industry would acknowledge that in issuing conditional registrations under FIFRA §3(c)(7)(A) or (B), the Agency will actually review only that data it finds necessary to make the incremental risk decisions called for by the statute.

(3) The industry and the Agency would agree that any applicant could properly satisfy its §3(c)(1)(D) data compensation obligations either by using the present "cite-all" approach or by submitting (or citing, with the original submitter's approval) sufficient satisfactory studies to meet the minimum data requirements applicable to the product for which approval is sought. Acceptance of this agreement by a data submitting firm would constitute a waiver of any entitlement to compensation for data considered by EPA. In other words, an applicant could "support" his application (for compensation purposes) with less data than the often more extensive set of data that could be used by the Agency to reach a scientifically sound registration decision. The arbitration procedure for dispute resolution, established by §3(c)(1)(D), would continue to be available.

EPA's concern, once again, is with ending the controversy in a way which preserves our ability to evaluate whatever data is necessary to reach sound decisions and to assure that our limited resources are efficiently used. Accordingly, this tentative settlement proposal would be acceptable only if all data submitters agree. Otherwise the change in approach would simply have the effect of substituting one group of plaintiffs for another. We continue to believe that our current policy is rational and lawful. A firm which places its interests as a data owner above its interests as an applicant might attempt to block a system under which its data could be "considered" without an "offer to pay" having been extended. Among the considerations we will be weighing as details of the proposal are worked out is the breadth of support among data submitters.

In preliminary discussions of this proposal to resolve the controversy, industry spokesmen have indicated a willingness to support a clarifying amendment to FIFRA which would make a clear distinction between data EPA may consider in making a registration decision and data relied upon by an applicant for §3(c)(1)(D) compensation purposes. While we are most reluctant to renew the extensive debate which preceded adoption of PL 95-396, if you and others in Congress are amenable to the very limited corrective action which has been mentioned, we would endeavor to obtain Administration support for such an amendment.

Further details of this approach would have to be worked out carefully. However, we believe that if the industry is willing to agree on such a system, the issues can be settled in a manner which meets the criteria for a workable registration process we have discussed earlier in this letter.

Before closing I would like to describe briefly our experience to date in registering products in accordance with the regulations at issue. As of November 1979, we have approved 163 amendments to existing product registrations, 7 for new uses of manufacturing use products and 156 for new uses of end use products. We have approved 529 new product registrations, 31 for new manufacturing use products and 498 for new end use products. This is a total of 692 registration actions approved under the May 11, 1979, regulations.

As you know, these regulations require registrants of manufacturing use products to acknowledge reliance on all scientifically pertinent data ("cite-all"). However, these regulations permit registrants of end use products to use an alternate method to "cite-all" for complying with the data compensation provisions of the Act in certain circumstances because of difficulties in establishing just which data are pertinent to end use product registrations and because of the potentially high transaction costs of using the "cite-all" approach for end use products. A comparison of the number of registration actions for end use products (both approved amended and new registrations) by method of data support shows that 65% (427) of the total 654 end use registration actions are based on the "cite-all" method.⁴ Thus, despite the controversy and litigation concerning the "cite-all" approach, in practice more registrants are choosing to rely on the "cite-all" method than on the alternate method. These registrants include several of those companies now actively engaged in the litigation.

We are extremely interested in discussing these issues and their possible resolution with you, your Committee colleagues and House of Representatives counterparts, and the Committee staffs.

⁴ The other 35% (227) of the end use registration actions are based on the alternate method (119), on a combination of the alternate method and the cite-all method (13), or on an old, now obsolete Option II (95), set forth in PR Notice 78-5. PR Notice 78-5 allowed the conditional registration program to begin while the interim final regulations were being completed. Product registrations issued on the basis of Option II are being changed to comply with the May 11, 1979, regulations.

Sincerely,

Steven D. Jellinek
Assistant Administrator
for Pesticides
and Toxic Substances

Mr. DE LA GARZA. Will the representatives of GAO kindly take the witness stand, identify yourselves and those who accompany you.

Mr. Wessinger, if you are going to make the presentation, you may begin.

STATEMENT OF HUGH J. WESSINGER, ASSOCIATE DIRECTOR, SENIOR LEVEL, COMMUNITY AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY LAWRENCE J. DYCKMAN, AND ROBERT E. ROBERTSON, SUPERVISORY MANAGEMENT ANALYSTS

Mr. WESSINGER. Mr. Chairman, let me introduce the team who worked on this review. On my far left is Bob Robertson, who was a team member. At my immediate left is Larry Dyckman, the team leader.

Mr. Chairman and members of the subcommittee, we welcome your invitation to discuss the preliminary results of our review of the Environmental Protection Agency's procedures for suspending a pesticide's use.

We began the review in response to a March 11, 1980, request from Congressman William C. Wampler, the committee's ranking minority member, who was concerned that EPA's emergency suspension of major uses of the pesticides 2,4,5-T and silvex may not have been based on scientifically validated studies.

We were also requested to explore whether there is a need to amend the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act concerning EPA's submission of a proposed notice of intent to cancel a pesticide to the scientific advisory panel for its review and comment before taking regulatory action.

First let me briefly mention some of the events that led to EPA's suspension of major uses of 2,4,5-T and silvex and its initiation of cancellation hearings on all uses of these pesticides. The herbicide 2,4,5-T has been used primarily to kill or control undesirable vegetation in forests, range and pasture lands, rights-of-way, and rice fields. Silvex has similar uses, including uses around the home and garden.

The toxicity of 2,4,5-T and its production contaminant dioxin became the focus of regulatory concern even before EPA had assumed responsibility for pesticide regulation, in December 1970. The U.S. Department of Agriculture, in early 1970, had suspended uses of 2,4,5-T in water bodies, around the home, and on food crops. EPA later allowed its use on rice fields.

In July 1973, EPA began cancellation proceedings against the remaining uses of 2,4,5-T including forestry, rangeland, rice, and rights-of-way uses. However, in June 1974, EPA discontinued the proceedings in order to obtain better monitoring data on the dioxin contaminant.

In April 1978, as part of an ongoing program to review the safety of pesticides in use, EPA started a Rebuttable Presumption Against Registration review of 2,4,5-T and the related dioxin-contaminated herbicide, silvex. EPA's presumption notice summarized extensive toxicity testing conducted by manufacturers, academic researchers, and the Government.

In June 1978, EPA received a letter from eight women living in the vicinity of Alsea, Oreg., who said they had experienced 10 mis-

carriages since 1973. The women claimed to be surrounded by forest land which had been sprayed for years with herbicides containing dioxin. In July 1978, as a result of the women's letter, EPA staff and contract personnel began an investigation to determine whether the reported miscarriages had any possible relationship to the 2,4,5-T sprayings. This investigation, referred to as Alsea I, involved administering a questionnaire to the women which asked about their pregnancies and sought information on their own and family medical histories, diet, and household pesticide usage. The results were evaluated by 10 experts including obstetricians and gynecologists. The reviewers concluded that they could not find a causal relationship between forest herbicide spraying and the miscarriages. On the basis of Alsea I data, no regulatory action was taken.

In late September 1978, EPA decided that a broader based epidemiological study on the possible relationship between the spraying of 2,4,5-T and miscarriages in the Alsea area was needed. Therefore, EPA, along with scientists associated with epidemiological studies programs at universities in Colorado, Florida, and Idaho began a study referred to as Alsea II.

The study's researchers collected data on 2,4,5-T use and on live births and hospitalized miscarriages in three areas: (1) The Alsea area; (2) a control area which, like the study area, is a rural region in Oregon but in which little or no use of 2,4,5-T had occurred; and (3) an urban area encompassing two Oregon cities. During January and early February 1979, EPA's contractors completed their reports and submitted them to EPA headquarters. Various EPA staff reviewed and edited the reports and EPA issued a final report on February 28, 1979.

The report concluded that there had been a statistically significant increase in miscarriages in areas where 2,4,5-T was used and that this increased correlated in time with 2,4,5-T spraying operations. The report added, however, that the analysis did not prove that 2,4,5-T caused the increase in miscarriages.

On February 28, 1979, the same date the Alsea II report was issued, EPA issued emergency orders immediately suspending forestry, rights-of-way, and pasture uses of 2,4,5-T and silvex. The silvex order also suspended home, garden, and several other uses. As required by section 6(c)(1) of FIFRA, the orders also announced EPA's intention to cancel the suspended uses of the two pesticides.

On March 6, 1979, Dow Chemical Co., and others challenged the emergency suspension orders in the U.S. District Court for the Eastern District of Michigan. On April 12, 1979, the court upheld the orders. Also, EPA suspension hearings began on April 19, 1979, but were discontinued on May 15, 1979, after Dow Chemical and other registrants withdrew from the hearings.

On December 13, 1979, EPA issued a notice of intent to hold hearings concerning all nonsuspended uses of pesticide products containing 2,4,5-T and silvex. On March 14, 1980, EPA began consolidated hearings on the suspended and nonsuspended uses of the pesticides to determine whether to cancel all uses of 2,4,5-T and silvex. EPA decided to consolidate the hearings to save time and allow for a more comprehensive and efficient review of the risks and benefits of the pesticides. EPA expects the hearings to last about 2 years.

To date we have concentrated on identifying EPA procedures for reviewing and validating epidemiological studies, such as Alsea II and determining whether EPA has followed its procedures. We have also examined EPA's reasons for not using its scientific advisory panel to evaluate either Alsea II or the other scientific evidence appearing in its February 28, 1979, notice announcing the emergency suspensions and intent to cancel certain uses of 2,4,5-T and silvex.

EPA has no written policy or procedures on whether or how to review and evaluate either the design or the results of epidemiological studies, such as Alsea II. EPA pesticide officials told us, however, that as a matter of practice they sometimes obtain peer reviews of a study's design before initiating the study and generally obtain peer reviews of study results after they are completed. The reviews are generally performed by two to four EPA scientists or consultants, who are considered experts on the subject matter but who have not been involved in the particular project being reviewed. The EPA pesticide branch responsible for overseeing Alsea II and similar studies has a list of consultants who, among other things, perform peer reviews for the branch.

EPA did not obtain peer reviews of the Alsea II study design. In late September or early October 1978, EPA officials decided that they wanted the study completed by about March 1, 1979, the start of the 2,4,5-T spraying season. According to the officials, this time constraint prevented them from obtaining peer reviews.

Concerning peer reviews of the study's results, EPA has little documentation showing what occurred. EPA pesticide officials said that they tried unsuccessfully to have outside scientists peer review the study results. The EPA officials responsible for obtaining the peer reviews told us he called approximately 10 to 13 scientists about 30 days before the February 28, 1979, suspension orders. To the best of his recollection none of the scientists were available to peer review the study within EPA's 30-day deadline. He added that he did not maintain a record of whom he contacted, precisely when he contacted them, or what their individual responses were. However, an EPA consultant, who is a member of the scientific advisory panel and several EPA scientists and technical staff persons reviewed the study's results.

FIFRA established the seven-member scientific advisory panel in 1975 to provide the EPA Administrator with advice on the impact actions proposed in a notice—to either cancel a pesticide or to hold a hearing to determine whether a pesticide should be canceled—will have on health and the environment. The act requires that at least 60 days prior to sending such a notice to the registrant or making it public, the Administrator give the panel a copy. The panel has 30 days to comment on the notice. However, the Administrator can waive the requirement for obtaining the panel's comments if the immediate suspension of a pesticide's registration is necessary to prevent an imminent hazard to human health. This is what happened to 2,4,5-T and silvex.

In issuing his February 28, 1979, suspension orders and notices of intent to cancel 2,4,5-T and silvex, the Administrator stated that he needed to immediately suspend the two pesticides to prevent an imminent hazard to human health. Accordingly, he waived the requirement for the panel's review.

EPA did not subsequently ask the Panel to review and comment on the February 28, 1979, notices. EPA's Office of General Counsel believes that the design of the cancellation and suspension provisions of the act establishes that the waiver of the Panel's review, once invoked, is intended to be permanent. EPA further believes that the statutory purpose disclosed by the act's legislative history indicates that the Panel's review was intended to provide predecisional scientific guidance on the question of whether a pesticide poses a threat of unreasonable adverse effects to human health and the environment.

At this point, we do not question EPA's interpretation of the law. However, based on our preliminary review of the events leading to the February 28, 1979, suspensions, we are concerned that there apparently was little independent scientific evaluation of important evidence EPA relied on when deciding to suspend the major uses of the two pesticides.

Our concern for independent scientific advice on important regulatory actions is not new. In a September 21, 1979, report to the Congress (CED-79-115) on improving the scientific and technical information available to EPA in its decisionmaking process, we recommended that EPA make more use of another EPA advisory group—the Science Advisory Board.

The Board, unlike the Panel which deals only in pesticide matters, can be requested by the Administrator to provide scientific and technical advice on any important environmental matter. We concluded that the Board, mandated by the Environmental Research, Development, and Demonstration Authorization Act of 1978, could provide valuable input into EPA's decisionmaking process on major actions dealing with scientific and technical information. EPA generally agreed with us.

Similarly, we believe that EPA should strike to make more use of the Scientific Advisory Panel on important pesticide regulatory actions. Therefore, at this point in our review, it seems to us that an amendment to FIFRA may be desirable to either (1) require the Administrator to seek the Panel's advice before issuing a final suspension order; or (2) require the Administrator to develop regulations to seek the Panel's advice before issuing a final suspension order.

We wish to stress that it is not our intent to delay the Administrator when he has decided that an imminent hazard exists. If, because of imminent hazard, the Administrator does not have time to submit a notice of intent to suspend or a suspension order to the Panel before issuance, the Administrator should submit the notice or the order to the Panel at the time of issuance.

Because of time constraints we were not able to obtain EPA's views on these matters. We believe, however, that this amendment should improve the decisionmaking process because it will give the panel an opportunity to comment before the Administrator renders a final suspension order following an expedited hearing.

Mr. Chairman, this concludes my prepared statement. We will be glad to respond to any questions you may have.

MR. DE LA GARZA. Thank you, sir. Mr. Wampler?

MR. WAMPLER. Thank you, Mr. Chairman. I would like to ask the General Accounting Office panel or task force this question. Do you think EPA had time to submit the so-called Alsea study to its Scientific Advisory Panel for comment as to its scientific validity before it issued the emergency suspension order on 2,4,5-T?

Mr. WESSINGER. From our conversations with EPA officials and representatives on the panel, it appeared that the panel would have been able to perform an expedited review of Alsea II study results. A draft of Alsea II containing the report's final conclusions was available some time in early or mid-February 1979.

Panel officials told us that they could have performed an expedited review of a study such as Alsea II in as little as 2 weeks.

Mr. WAMPLER. Let me ask you this. It is my understanding that the General Accounting Office completed another review of EPA in September 1979 that dealt with improving the scientific and technical information available to EPA in its decisionmaking process and that you found that it was inconclusive and in many cases perhaps it hindered their ability to make complete technical decisions. As a result, this brought about numerous court suits and that you made certain recommendations.

Would you care to comment on what you recommended at that time?

Mr. DYCKMAN. Yes; thank you, sir.

In our previous report, that you are referring to, we actually did not find a significant number of court cases involving questions of the adequacy of scientific evidence surrounding EPA decisions. I believe that was a National Academy of Sciences conclusion.

We did, however, conclude that EPA has only made limited use of its Science Advisory Board to provide the Administrator with the independent scientific advice that he needs.

Also, in comparing the results of our present review and our past review, I would like to say that we are concerned that EPA's procedures for obtaining independent scientific advice needs to be improved. While there are differences between the scope of our prior report and the scope of the investigation that we are doing now, we do see a common thread, which is a need for more and better independent scientific advice to the Administrator.

Mr. WAMPLER. Mr. Chairman, I think those are all the questions I have at the moment. Perhaps some other member of the committee wants to ask some.

Mr. DE LA GARZA. Mr. Fithian?

Mr. FITHIAN. No.

Mr. DE LA GARZA. Mr. Brown?

Mr. BROWN. No.

Mr. DE LA GARZA. You say that this is an incomplete review of the process. How much further and in how much more depth do you intend to pursue this review?

Mr. WESSINGER. This is something about which we hope to meet with Congressman Wampler's staff after the hearing to reach some kind of agreement on how much further he would like us to pursue this investigation.

Mr. DE LA GARZA. Also, you stated that they did not use the Advisory Panel to evaluate. I think that Mr. Jellinek said and I remember from the hearings that of the members of the Advisory Panel a Dr. Davies, the epidemiologist, was consulted. Is that the case?

Mr. DYCKMAN. Yes: there is no question that Dr. Davies reviewed the results of Alsea II. It is our understanding that he did not review it as a member of the Scientific Advisory Panel. I believe this is what the panel testified to last year before the subcommittee.

Mr. DE LA GARZA. How do you distinguish? The man is a member of Panel and he is consulted by EPA.

Mr. DYCKMAN. That is right. We have not had an opportunity to talk to him directly.

First let me say that, although I do not recall his precise background, he represents one scientific discipline. He is an epidemiologist. The Alsea II study, as we understand it, comprised basically two scientific disciplines—epidemiology and statistical analysis.

The Panel would have preferred to have received the report as a whole and we would support that—

Mr. DE LA GARZA. Where does that information come from?

Mr. DYCKMAN. We spoke with the Panel's vice chairman and the vice chairman also testified, I believe, last year before this subcommittee.

Mr. DE LA GARZA. He did testify here that they would—

Mr. DYCKMAN. Let me just add one more thing, Mr. Chairman. We questioned Dr. Duncan, who was one of the authors of the report, and we asked him very carefully whether he felt Dr. Davies' review of his work was a peer review in the formal sense. He said he did not think it was a peer review but more of a supervisory review.

One of the objectives of our investigation for Mr. Wampler was to try to determine whether or not there were in fact formal peer reviews of Alsea II prior to the suspension.

Mr. DE LA GARZA. But you never spoke to Dr. Davies?

Mr. DYCKMAN. He was out of the country. He may have recently returned.

Mr. DE LA GARZA. Mr. Fithian?

Mr. FITHIAN. Thank you for yielding, Mr. Chairman.

My point was that we have a Scientific Advisory Panel and they are all different kinds of scientists. If they went to the person on the Panel who was the expert in this field, are you not stretching this issue to say that they did not consult or that they did not have peer review?

Moreover, I think it might give a little more accuracy to your recommendations if you indicated that, while you have not yet talked to the expert, that that is your intention because to go to someone else—you know how it is, I used to be a professor, you are going to feel slighted if you were not consulted.

However, if they went to the guy who is the expert in the field, I think that is at least part of what we intended—and it was my amendment that put this Scientific Review Panel together.

I respect what Mr. Wampler is trying to do, although I will have more to say about that when we come to it. I just do not think we ought to leave the impression here that there was no consultation and I think that is basically what we are getting.

Mr. DYCKMAN. We did not intend to imply that there was no consultation with any members of the Panel, but it is correct to say that the Panel as a whole was not consulted. That is primarily our point.

Mr. DE LA GARZA. The legislation did not intend that they unite or call the Panel to meeting. My personal interpretation of the testimony was similar to Mr. Fithian's that the vice chairman says, "I am the vice chairman and I was never consulted and we did not act as a panel."

However, the only expert was the one that acted, so we may be dealing in semantics here.

Mr. DYCKMAN. One additional point is that when the Panel meets it hears industry representatives and it also hears EPA present its case before the Panel. It is not an adversary type of meeting but, I think, in the case of an open meeting—which did not occur—there would have been more ventilating of the scientific issues involved in Alsea II.

Mr. DE LA GARZA. I do not think it was ever the intent of the legislation to have a confrontation between industry and EPA before the Advisory Panel. I think you are stretching or perhaps interjecting your own personal opinions as to what was the intent of the law.

Mr. WAMPLER. Mr. Chairman, will you yield?

Mr. DE LA GARZA. Yes.

Mr. WAMPLER. I have to respectfully disagree with you. I think the statute is very specific on what the function of the Scientific Advisory Panel is. They are supposed to have a public hearing very similar to what we are having right here today where all interested parties will have a chance to come in and be heard.

It is not necessarily an adversarial proceeding.

I think what we are talking about here is: What is a legal definition of peer review? FIFRA is very specific. It says:

The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the actions proposed and notices of intent issued under section 6(b) of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture.

Mr. DE LA GARZA. The gentleman is correct. Both the gentleman from Indiana and I appreciate and understand the law. What I was trying to imply to the gentleman is that his opinion was that this was where industry comes to rebut. That is not the intent of the law.

Mr. DYCKMAN. I am not an attorney, so I guess I should not offer an opinion, and I will not, on the intent of the law. However, when the Scientific Advisory Panel meets they meet after public notice and they invite public participation.

Mr. DE LA GARZA. Right. That is the intent of the law.

Mr. DYCKMAN. Yes; I think we could all agree on that. All we really want to say here is that that did not occur in the case of Alsea II. We are not really offering a value judgment in terms of the quality of the study or of the shortcomings that that meeting's not taking place resulted in.

Mr. DE LA GARZA. If you all would kindly take a seventh inning stretch, we will go and vote and be right back.

[Recess taken.]

Mr. DE LA GARZA. The subcommittee will be in order.

Do you have any further comments?

Mr. DYCKMAN. I just want to clarify one point. I did not intend to mislead the committee by implying that the Scientific Advisory Panel conducts hearings. They conduct open meetings at which members of the public are invited to participate and present their opinions. It is not an adversary type relationship.

If I misled the committee in that regard, I am sorry. I did not mean to.

Mr. FITHIAN. Mr. Chairman?

Mr. DE LA GARZA. Mr. Fithian.

Mr. FITHIAN. May I ask Dr. Johnson or someone from the EPA just one factual question. It has to do with whether or not in the

creation of the Scientific Advisory Panel you set up this process of all sides being heard at a public hearing either by charter—I am looking in vain for that provision in the amendment which I authored.

Mr. JELLINEK. Mr. Fithian, we did not set that process up for an open meeting. That aspect comes from an earlier Advisory Committee Act and under the procedures of the committee they decided that members of the public would participate. It is required of them to allow members of the public to make statements under the Advisory Committee Act.

Mr. FITHIAN. I want to comment and Mr. Bor advises me that my impression is correct. The purpose of the Scientific Advisory Panel, I would advise the witnesses, came about because some of us—I believe that the ranking member, the distinguished member from Virginia, supported that notion—felt that the EPA was not going to the real scientific talent in America to make those decisions, that we were having a bit too legalistic a twist.

We felt they were not always taking the best scientific advice that was available, so we created the Scientific Advisory Panel upon an amendment which I offered in full committee. The purpose was not to have a bunch of lawyers, if you will pardon the phrase, come in and argue over something. Rather it was to sit down and see whether or not by the best scientific data available EPA was making its judgments, calling its shots, on the basis of real hard science as best they could and as best we all could in a very indefinite field.

That was the purpose of the Scientific Advisory Panel. If we have had some other accretions along the way so that it has gotten sort of like an administrative law judge proceeding where you bring in both sides and you argue the case, then I would submit that is a perversion of the intent of the Scientific Advisory Panel which was never intended to do that.

It was purely and intentionally to go to the best scientists we could command and say—for we are not scientists on this committee—“Are we using the best scientific data in making this decision on the protection of the environment and yet allowing the widest possible use of safe chemicals?” That was the purpose behind it.

We may need, Mr. Wampler, some adjustment to the role and more specificity of the role of the Scientific Advisory Panel. I have some serious questions as to whether we need another one on top of what we already have, which is what I think we are all tending to argue for here.

I will speak to the amendment a bit later. I just wanted to express, as the author of the amendment, what the original conception was and I am not sure that our friends from GAO understood that.

Maybe, Dr. Johnson, you say that it is something you directed your Advisory Panel—or maybe the Advisory Panel said, “Now we are going to set ourselves up as administrative law judges.” If that is the case, that is not what the law had in mind and it is not what the law requires.

Mr. WAMPLER. Mr. Chairman?

Mr. DE LA GARZA. Mr. Wampler.

Mr. WAMPLER. It is my contention in the case of the suspension of 2,4,5-T that there was no proceeding as far as the Scientific Advisory Panel is concerned. They consulted with one member of the Panel,

which as I understand this case, was the supervisor of the person who conducted one of the Alsea studies.

I am not alleging any improper relationship. What I am saying is that there was no proceeding as required under FIFRA, as amended.

I would like to ask Mr. Jellinek this. Do you consider that you followed that section of the law? Did you have a proceeding? Did the Scientific Advisory Panel comply with the law and did you comply with the law?

Mr. JELLINEK. Mr. Wampler, I think that the best way to answer that question is to refer to a memorandum of May 4, 1979, which I would be happy to make available to the committee.

It is from the executive Secretary of the Advisory Panel to Mr. David Menotti, our Assistant General Counsel. Let me just read the pertinent parts of the memo.

The opening paragraph says:

This is to clarify the role of Dr. John Davies, a member of the FIFRA Scientific Advisory Panel, as a witness in the ongoing proceedings on 2,4,5-T and Silvex.

I am skipping a couple of background paragraphs.

Dr. Davies explained to EPA staff who initially contacted him regarding reviews of the scientific basis for regulatory action on 2,4,5-T and Silvex that his participation would be that of an official member of the Panel and not as an independent consultant. He has restated his position several times to members of the Office of General Counsel. This position is fully supported by Dr. Torgeson, Chairman of the Scientific Advisory Panel, who has requested that Dr. Davies prepare a full report for presentation to the Panel and ultimate publication in the Federal Register as an advisory report of the Panel.

I think we were under the impression from discussions with Dr. Davies and the Panel itself was under the impression that Dr. Davies was participating as a formal, official member of the Panel.

Mr. DE LA GARZA. Without objection, the letter will be included in the record at this point.

[The letter referred to above follows:]

U.S. ENVIRONMENTAL PROTECTION AGENCY,
OFFICE OF TOXIC SUBSTANCES,
Washington, D.C. May 4, 1979.

Memorandum

Subject: Participation of Dr. John Davies as a Witness in 2,4,5-T and Silvex Proceedings.

From: Executive Secretary, FIFRA Scientific Advisory Panel (TS-766).

To: Mr. David Menotti, Assistant General Counsel for Pesticides.

This is to clarify the role of Dr. John Davies, a member of the FIFRA Scientific Advisory Panel, as a witness in the ongoing proceedings on 2,4,5-T and Silvex.

Authority for participation of Dr. Davies in the proceedings on 2,4,5-T and Silvex is presumed to be contained in the following responsibility of the Scientific Advisory Panel as mandated by Congress in Section 25(d) of FIFRA, as amended:

* * * "The Administrator shall also solicit from the Advisory Panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the Advisory Panel and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections."

Dr. Davies explained to EPA staff who initially contacted him regarding review of the scientific basis for regulatory action on 2,4,5-T and Silvex that his par-

ticipation would be that of an official member of the Panel and not as an independent consultant. He has restated his position several times to members of the Office of General Counsel. This position is fully supported by Dr. Torgeson, Chairman of the Scientific Advisory Panel, who has requested that Dr. Davies prepare a full report for presentation to the Panel and ultimate publication in the Federal Register as an advisory report of the Panel.

In order to avoid future confusion regarding transmission of official business of the Panel, you should ensure that all actions are coordinated with the Secretariat of the Panel. Individual members of the Panel do not desire nor are they authorized to make independent judgements in the name of the Panel. Hopefully, all concerned parties in OPP and OGC will keep this in mind. Members of the Secretariat will continue to make every effort to fully cooperate with all parties to ensure expeditious discharge of Panel responsibilities as specified in the Act.

For the Chairman :

H. WADE FOWLER, Jr., Ph. D.,
Executive Secretary,
FIFRA Scientific Advisory Panel.

Mr. WAMPLER. Mr. Jellinek, let me ask you this question. Did you depart in your proceedings to cancel 2,4,5-T from that of any other proceedings of like nature? Did you follow the same process as you did in the others or did you depart from the previous processes?

Mr. JELLINEK. That proceeding was an emergency suspension. Since it was the first emergency suspension, we did waive the formal requirement, as we were permitted under the law to do, to consult formally with the Panel. However, we did follow a process that we thought was a functional equivalent of that.

In every other decision to cancel a pesticide, a proposed cancellation of a pesticide pursuant to an RPAR, in every rule and regulation that we have proposed since the 1975 amendments, and in every final RPAR cancellation proposal and final regulation we have followed the procedure laid down by the law and consulted the Scientific Advisory Panel.

Mr. WAMPLER. It would be fair to say, would it not, that in the case of 2,4,5-T you relied on scientific evidence which was the Alsea II study. Is that correct?

Mr. JELLINEK. That was one part of the evidence. As we said in our statement on the suspension, that was an important addition to the body of laboratory evidence and our concerns about the exposure of people to 2,4,5-T and silvex that—

Mr. WAMPLER. Are you familiar with the study that was conducted at Oregon State University on this question?

Mr. JELLINEK. I am generally familiar with it. I have not read it in detail, but I am familiar with its conclusions.

Mr. WAMPLER. I still say, Mr. Chairman, that the statute was not followed in this case, particularly as it pertains to the Scientific Advisory Panel. My concern is that I do not want to see any pesticide canceled on the basis of doubtful scientific judgments and studies.

It looks to me as though we need to tighten up the statutory language here to require you to do certain things before taking such drastic action.

If I understand the situation correctly and your present hearing procedure, EPA has budgeted and is going to spend many thousands of the taxpayers dollars pursuing this. I certainly do not want to second guess what the results are going to be, but in my opinion you are going to get right back to point zero.

The private sector, if I am advised correctly, is going to likewise be spending many thousands of dollars needlessly. This Congress has

been spending long hours this week trying to pass a budget resolution which, hopefully, will balance the budget.

I would just like to say respectfully that there are areas like this where we are needlessly spending our resources. We ought to be using our dollars for better purposes. I say this in a critical vein because I think it was a bad decision and that you did not follow the law, in my opinion, particularly in getting the advice of your full advisory panel.

Mr. JELLINEK. I would like to respectfully agree with your conclusion and intent that we should not make decisions on the basis of doubtful data but disagree that we did not follow the law in this case. I think we followed the letter of the law with respect to emergency suspensions and I think we followed the spirit of the law in an attempt to get the best outside advice we could given the limited time and circumstances.

We also, as I said and would like to emphasize, tried to obtain independent advice from within EPA that was not related to this decision or even this program. We asked scientists from other programs to meet with us on an expedited basis. I want you to know that I personally was involved in grilling those scientists. Many of them worked long hours. In fact, one of them worked through the night in an attempt to critique the Alsea study to be prepared for an all-day-Saturday meeting which we had, at which I grilled not only Dr. Duncan but also the other EPA scientists who were involved to try to make sure that we did have a reasonable basis on which to proceed.

As we said publicly when we suspended the chemical, the Alsea study did not prove causality. We recognized right from the beginning that we did not have a clear cause and effect relationship, but we thought we had a reasonable basis on which to take the suspension-action, given the fact that it was a temporary action, and that the cancellation procedures and suspension procedures of the act would provide ample opportunity to go into great detail on whether or not the facts merited final termination.

I think that based on the information available to us at that time and the fact that we were trying to make a decision before large-scale spraying began, we did the right thing. I think that events will prove that that decision was correct as the Alsea study gets critiqued and as additional information about the effects of 2,4,5-T, both from the Alsea, Oreg., area and from other areas in other studies, is developed and critiqued and analyzed through the cancellation hearings that are now underway.

Mr. WAMPLER. Mr. Jellinek, I have prepared an amendment to be offered at the appropriate time. What it attempts to do is to say that whenever the Administrator of EPA exercises his authority under section 6(c) of the act to immediately suspend registration of any pesticide because of an imminent hazard, he shall promptly submit to the Scientific Advisory Panel for comment to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

It just seems to me that in the case of 2,4,5-T you acted on the basis of scientific data that was not convincing. It had not had adequate peer review. This is the point I am making.

I am not just criticizing EPA. I have criticized other agencies in that regard. I just think there is a better way to do it. That is why I want to tighten up the statutory language to be sure that you submit that and do it promptly and that we have the best scientific data, opinion, and peer review that we can before making these types of decisions.

This decision of suspension has cost certain sectors of agriculture an awful lot of money. I am told there is no single pesticide now that can be used in silva culture and that you perhaps would have to use four or five different ones, applying them at different times, and you might be doing more damage to the environment that way than using one single pesticide. That is just a supposition of mine. I have no data on that.

The point is: I think there is a better way to do it. I just feel that EPA did not follow the intent of the law.

Thank you, Mr. Chairman.

MR. DE LA GARZA. Where are we in the process now, Mr. Jellinek? Is this before an administrative law judge?

MR. JELLINEK. Yes, sir. As you may recall, after the district court in Michigan upheld our suspension order we began suspension hearings, as required by FIFRA, but the registrants withdrew from the suspension hearings. They would have, of course, provided another expedited opportunity to review the Alsea study and EPA's other data, but the registrants withdrew and the suspension hearing was terminated because of that.

At that point, we began to prepare for the cancellation hearing and that hearing began a month or so ago. Testimony is now being taken on the various issues. We expect that it will probably take another year to a year and a half, closer to a year and a half, to complete the formal cancellation hearing. There are literally dozens of witnesses on both sides, approximately 150 witnesses total, and that is just on the risk side of the issue. The benefit side will include even more witnesses.

MR. DE LA GARZA. The odds are that regardless of what the scientific review would have been, we would be at the same stage, nonetheless, in the administrative procedure.

MR. JELLINEK. I am not sure I understand your question.

MR. DE LA GARZA. If you had acted with all of the scientific data and all the peer reviews, you would still have gone to the next administrative step—

MR. JELLINEK. Yes; my assumption is based on Dr. Davies' conclusions and the conclusions of our other independent EPA scientists that we would have received the same general advice and that if we had we would have gone ahead as we did.

MR. DE LA GARZA. Let me ask the GAO spokesmen this. What is your interpretation of peer review?

MR. DYCKMAN. First, it is not a GAO term. It is a term that we obtained from EPA scientists and from scientists at other agencies. It has been explained to us that it is a process by which an eminent scientist who is an expert in his field and has not worked on the particular project that is under review, reviews that study's results. It can be a review of the study's results or a review of the study's design or protocols. The scientist then offers his comments to the author or the agency that is sponsoring it. The agency or author reviews those comments and determines whether the final report should be changed.

Mr. DE LA GARZA. What I would like to get at is this. Do we have a scientist's review, who then is reviewed by other scientists, who then are reviewed by other scientists? Where does the peer review end? Is there a number?

Mr. DYCKMAN. EPA told us that they do not have written procedures but they normally obtain two to four peer reviewers, either outside of the agency or within the agency.

Mr. DE LA GARZA. You say in your statement here that "apparently little independent scientific evaluation of important evidence EPA relies on within deciding," et cetera. The testimony from the hearing with Dr. Neal, on a question by Mr. Grassley about whether they were consulted, says:

No; they did not, although they consulted Dr. Davies as an independent epidemiologist as they did epidemiologists around the country. They did in fact, however, provide us the data base on which the decisions were made but did not solicit advice from us relative to the adequacy of that data.

I think Dr. Neal and I had a dialog on that. Why would they send it to you if they did not want you to comment?

Mr. DYCKMAN. Let me comment on your first point. An EPA official told us that he did in fact try to obtain scientists throughout the country to review the results of Alsea II but was unsuccessful except for Dr. Davies.

As far as we know, concerning your second point, the Scientific Advisory Panel did not in fact review the results of Alsea II.

Mr. DE LA GARZA. They received the data according to Dr. Neal.

Mr. DYCKMAN. If he said it, I am sure it is true. However, there was no official meeting of that Panel.

Mr. DE LA GARZA. Did you review the record in your examination for this report of the proceedings of the—

Mr. DYCKMAN. Yes; I believe I have a copy of it with me. Do you mean his testimony before this committee?

Mr. DE LA GARZA. Yes.

Mr. DYCKMAN. Yes.

Mr. DE LA GARZA. He says that they did submit it to him. His argument was that they had no formal meeting.

Mr. DYCKMAN. Right. It is our understanding that generally the Scientific Advisory Panel will not on its own, conduct a review of a particular subject unless it is requested to by EPA; and EPA did not request it to review Alsea II.

Let me just add also that I think the thrust of our statement was not so much at Alsea II but at the notice of intent to cancel and notice of the suspension order. The Panel did not review that document. EPA waived the review because of imminent hazard.

We are suggesting that it may be beneficial to have an amendment to require the Scientific Advisory Panel to review those documents concurrent with an emergency suspension or any type of suspension wherein EPA feels that they have to act on an imminent hazard. We are trying to differentiate in our testimony between an amendment to have the Scientific Advisory Panel review the entire notice of intent to cancel or the entire notice of intent to hold hearings to cancel a pesticide, as opposed to its review of a particular study.

Mr. DE LA GARZA. Are you acquainted with the law—section 6(b)(2) that gives them the authority for emergency actions without consulting the Advisory Panel?

Mr. DYCKMAN. Yes; that is correct. We are.

Mr. DE LA GARZA. Your recommendation to us in that we provide an emergency procedure that includes participation by the Advisory Panel. Is that it?

Mr. DYCKMAN. We do not intend for the Administrator to delay his decision on declaring an imminent hazard. We feel that there may be good reason for the Scientific Advisory Panel to review that document after the suspension order is issued or after a notice of suspension is made public. As we see it, it would not interfere with the Administrator's ability to act on an imminent hazard. He would either order an emergency suspension, as he did in the case of 2,4,5-T, or in a normal suspension he would issue a notice of intent to suspend it. While expedited hearings take place, if requested by a registrant, the Scientific Advisory Panel could, if they have time, review the evidence relied on by the Agency in reaching that suspension decision.

Mr. DE LA GARZA. Did you say you were not an attorney?

Mr. DYCKMAN. That is correct.

Mr. DE LA GARZA. I said what you recommended was an emergency procedure and then you took 2 minutes to repeat what I said. [Laughter.]

Mr. DYCKMAN. I want to make sure that the Chair understands what our proposed amendment is.

Mr. DE LA GARZA. You said the same thing but it took you longer.

Mr. DYCKMAN. I probably do not have your ability to summarize.

Mr. WAMPLER. Mr. Chairman?

Mr. DE LA GARZA. Mr. Wampler.

Mr. WAMPLER. I would like to make one unanimous consent request. I would like to ask that the memorandum from which Mr. Jellinek quoted be included in the record in its entirety and also, Mr. Chairman, that we keep the record open for the possible inclusion of a letter from Dr. Davies to Dr. Torgeson that was referred to earlier.

Mr. DE LA GARZA. That will be allowed without objection. I believe the memorandum quoted by Mr. Jellinek may have already been submitted.

[See p. 186.]

Mr. DE LA GARZA. A copy of the portion of Dr. Neal's testimony from which I read will also, without objection, be included in the record at this point.

(The following excerpt is taken from the hearing Serial No. 96-0, Fifra Extension, pp. 26 and 27, held before the Subcommittee on Department Investigations, and Research, Apr. 24, 1979:)

Mr. Grassley?

Mr. GRASSLEY. Thank you. Dr. Neal and Dr. Davies. Congressman Wampler has not been able to appear yet. He had two questions he wanted to ask you with three subparts in one of them and two subparts in the other.

I would like to ask these questions for Congressman Wampler. It happens that the first one touches a little on the point that Dr. Davies just made. I think for the consistency of the record I will ask the question again so it can be answered in the context that Mr. Wampler would have asked it.

Recently, Environmental Protection Agency took emergency action to suspend two herbicides commonly known as 2,4,5-T and Silvex. Recognizing the fact that EPA is not required under law to consult the Panel during an emergency suspension, Mr. Wampler's first question is: Did EPA consult the Panel and, second, did EPA have time to consult the Panel, and, third is not this particular action of the type that the Scientific Advisory Panel was designed to give scientific advice or opinions on?

Mr. NEAL. The first part of that question, did EPA consult the Panel? No, they did not, although they consulted Dr. Davies as an independent epidemiologist as they did epidemiologists around the country. They did, in fact, however, provide us the data base on which the decisions were made but did not solicit advice from us relative to the adequacy of that data base for the decisions that they reached.

As for the second part of that question, did the EPA have time to consult the Panel? Yes, they did. You can have emergency meetings on a weekly basis kind of thing so that they could have solicited our advice relative to this issue.

Then the third part of it is the part that I directed some remarks to earlier and that is, isn't this particular action the type that the Scientific Panel designed to give scientific opinions on: and I would say that, yes, it is.

We do not want to interfere with the ability of the Administrator to cancel or suspend chemicals if necessary to prevent human health effects.

It is just that we think subsequent to that action he should have available the ability to do that suspension or cancellation, but we think the scientific issues on which that issue was based should be clarified in submitting that data to the Panel for evaluation.

Mr. WAMPLER. Let me ask one final question, Mr. Chairman.

If I may, Mr. Jellinek, how much money does your Agency have budgeted this year for the cancellation proceedings?

Mr. JELLINEK. Mr. Wampler, I cannot give you a precise answer on that right now. We can try to add it up. It is a lot of money. We have probably an average of 12 to 15 EPA employees working on it full time and maybe more. We are paying travel expenses for witnesses and for witness fees and things like that, so it is a lot of money.

We can try to estimate it if you want to hold the record open and can get it to you.

Mr. WAMPLER. Do peer review costs go into that account or under that general heading in the expenses of your Agency?

Mr. JELLINEK. The outside peer review is usually done through an outside arrangement with an outside scientist. Inside peer review is done through normal salaries and benefits.

Mr. WAMPLER. And it is the practice of EPA in cancellation hearings of this nature to permit so-called public organizations to come in. Do you pay their travel expenses or pay them fees for testifying? Do you do that to get a balanced record or something like that?

Mr. JELLINEK. Are you talking about the witnesses who testify at these hearings?

Mr. WAMPLER. Yes, sir.

Mr. JELLINEK. We do whatever the normal Government procedures are for paying travel expenses and witness fees for extra witnesses in these types of administrative proceedings. There is no intervenor funding, if that is what you are getting at.

Mr. WAMPLER. That was what I was getting at.

Mr. JELLINEK. There is no intervenor funding.

Mr. WAMPLER. I would appreciate it if you would supply for the record just what you are spending in fiscal year 1980 and what you propose to spend in later fiscal years, as well as what you have spent in prior fiscal years on the broad question of the cancellation of 2,4,5-T. Give us an estimate, as best you can, of the man years or man hours, or however you compute it, man days.

Mr. JELLINEK. We will attempt to do that as best we can.

Mr. WAMPLER. Thank you.

Mr. DE LA GARZA. Thank you.

Do you have any further comments, Mr. Jellinek?

Mr. JELLINEK. No; except that we have had an opportunity to review the proposed amendment and, as you might suspect, we oppose it. We think, frankly, that it is unnecessary and also that it is redundant. It would add another provision for reviewing Agency decisions on top of a whole series of review provisions that already exist and that we have discussed at some length. We, frankly, think that it would add more cost to the process in addition to the already expensive process that we now operate when we suspend or cancel pesticides. However, I do not want to go into any more detail. If the committee would like some more I can provide it for the record or I can go into it now.

Mr. DE LA GARZA. Thank you very much, sir.

And we thank you gentlemen from the GAO for your participation. We appreciate your being here. Thank you very much.

Mr. Fithian has a further question of the EPA.

Mr. FITHIAN. Either Mr. Jellinek or Mr. Johnson, or both, can respond.

Mr. Chairman, I would ask at this point to insert into the record a letter addressed to the chairman of the subcommittee, dated April 24, from Elanco, because of the importance of the issue that we should try to establish here.

Here is a little bit of background, Dr. Jellinek. When we did all of these things to FIFRA in 1978 we were very concerned that we not snuff out research and that we provide experimental use permits for a whole variety of uses, rather than to wait until it was tested broadly in the field. Thus, we provided in the law for the environmental use permit.

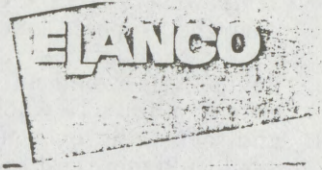
Now, I have discussed this with the Elanco people, as has my staff. For the purpose of passing along the information to other members of the subcommittee, I cite only a portion of the letter but I am asking that the full letter be made a part of the record at this point, Mr. Chairman.

Mr. DE LA GARZA. Without objection, it will be made a part of the record.

[The letter referred to above follows:]

Elanco Products Company
A Division of Eli Lilly and Company

P. O. Box 1750
Indianapolis, Indiana 46206
Telephone (317) 635-8400



April 24, 1980

The Honorable E. de la Garza
U. S. House of Representatives
Chairman

Subcommittee on Department Investigations, Mail
Oversight and Research of the
Committee on Agriculture
Room 1434, LHOB
Washington DC 20515

APR 28 1980

Interest _____
FYI _____
Staff _____

Dear Mr. Chairman:

During the recent hearings which your subcommittee held on FIFRA, there was one issue which was not addressed but is of considerable concern to many of us in the pesticide industry. Elanco supports the comments presented by NACA but we are also deeply concerned about the efficiency and utility of the Experimental Use Permit (EUP) Program under Section 5 (a) of FIFRA as it is currently being administered by the Agency. The EUP system is not functioning in a manner conducive to the enhancement of research and development of new and better pesticides. In our opinion, the EUP program is not satisfying the intent of Congress and the spirit of the requirements of amended FIFRA. Research and development is being shackled and discouraged. Here are some of the reasons:

1. Requirements to obtain a first experimental use permit on a food crop are increasing to the point that they are beginning to approach the requirements for conditional or full registration.
2. Expenditures required by the registrant in order to obtain an experimental permit before he knows whether or not he has a viable potential product are excessive.
3. Temporary tolerance requirements for a food crop are nearly the same as for a full tolerance. Detailed residue methodology, residue monitoring and plant and soil metabolite identification are required long before the registrant knows the product will really perform under actual field conditions.

Rep. E. de la Garza
 April 24, 1980
 Page 2

These requirements lead to excessive costs and erode the spirit of the EUP program without justification.

4. Excessive time delays in receiving an EUP discourage research and development for marginally economic products but which may be very important to agriculture.
5. Patent life is eroded and valuable marketing years are lost. Here are some examples.
 (We have attempted to allow for EUP delays which were due to our fault in our assessments of lost marketing years.)

Product A

585 days have elapsed since submission for an EUP, and it has not issued. Estimated loss of market to date due to excessive delays is \$3,000,000. One year of patent has been lost.

Product B

470 days have elapsed since submission for an EUP, and no permit. Estimated loss of market to date due to excessive delays is \$36,000,000. One year of patent lost.

Product C

1,273 days elapsed before permit was issued. Since that time, a request for renewal has been filed for; 286 days and still no EUP. Estimated loss of market to date \$18,000,000. Two years of patent lost.

6. Moving targets for data requirements are impossible to cope with. A registrant must guess what is going to be required for an EUP and then submit his data accordingly. The Agency is constantly changing its EUP requirements making it practically impossible to obtain an EUP in a reasonable length of time. EUP guidelines have not been finalized.

Rep. E. de la Garza
April 24, 1980
Page 3

We suggest the EUP program could be improved if the Agency would:

1. Provide a separate tracking system for EUP's to be administered separately from full registration review work.
2. Improve follow-up. Avoid unnecessary delays. Documents have been lost or misplaced for considerable periods of time.
3. Provide for more flexibility in granting EUP's for compounds of known chemistry.
4. Be more flexible in granting temporary tolerances. A phased program tied to the amount of pesticide requested and to the magnitude of residues has been suggested, but there has been no agency response.
5. Establish EUP guidelines to alleviate the guessing game and moving targets.

Mr. Chairman, we respectfully submit these concerns and suggestions and hope that they will help to improve the Experimental Use Permit Program which is so vital to productive research and development pursuits within our industry. If the industry is to discover and develop new, safer, more environmentally compatible agricultural chemicals, research must be encouraged, not regulated out of existence. New and improved technology for the American farmer must not be jeopardized or unnecessarily delayed.

Very truly yours,

ELANCO PRODUCTS COMPANY

David L. Wothke
Director
Industry Affairs

DLW:br

cc: Dr. J. D. Early (NACA)
Rep. Floyd Fithian
Rep. Tom Foley
Sen. Dick Lugar

Mr. FITHIAN. At the bottom of page 1 the comment is made: "Temporary tolerance requirements for a food crop are nearly the same as for a full tolerance."

No. 4 on page 2 indicates another problem with EPA's granting of environmental use permits. It is labeled "Excessive Time Delays in receiving an EUP discourage research and development," which is the key to my concern. I do not want us to do things which will discourage research and development: " * * * discourages research and development for marginally economic products, but which may be very important to agriculture."

On the bottom of that page—and this is a rather serious criticism, I think, of the process, and I would hope that we can nail this down—No. 6:

Moving Targets for data requirements are impossible to cope with. The registrant must guess what is going to be required for an EUP and then submit his data accordingly. The Agency is constantly changing its EUP requirements, making it practically impossible to obtain an EUP in a reasonable length of time. EUP guidelines have not been finalized.

First, I would like you to comment on the criticism that is made, and second—and then I will close part of this because this is the end of it—I have the two recommendations that they have passed along which seem to me to be eminently reasonable.

No. 1 was to provide a separate tracking system for the EUP to be administered separately from full registration review work. No. 4:

* * * be more flexible in granting temporary tolerances. A phase program tied to the amount of pesticide requested and to the magnitude of the residues has been suggested but there has been no Agency response.

I would recall, Dr. Johnson, for I know that we engaged you in this conversation 2½ years ago at some great length, the necessity for flexibility and the necessity for EPA to give consideration to the amount. I think you recall the discussion of something to be used on a small peach orchard to be tried, something to be used by Ag experiment stations, and all of those discussions that we had at great length.

I would appreciate a comment from the Agency on what I think is a rather serious matter which we have not addressed previously in these hearings.

I apologize to the Chairman for bringing this up at this late hour, but there has been no other time when we could really get a clear shot at it.

Mr. JOHNSON. I appreciate the opportunity to comment on this, Mr. Fithian. Mr. Stickle gave this to me some half-hour ago, so I did take a look at it prior to your asking me to comment.

I have to say that I am not personally happy with the responses that we have been able to make in the experimental use permit program and we are making several improvements in that process. However, I do obtain periodic reports on the movement of things through that process and as a general rule we do not take the lengths of time that are laid out in this letter. I am frankly appalled to see that length of time.

There are, I suspect, people who have come in for experimental use permits and have had them denied at one time or another. That denial counts as a decision. They may have had to resubmit additional data

and ask for another EUP. I am not sure exactly what the situation is here, but I can assure you that I will go back and look into these three specific cases.

We are taking several steps, as I said, to try to improve our handling in this area. We set up a new priority tracking system which does do much of what has been suggested in item 1 of this letter. We will establish times and priorities for registration actions, including experimental use permits.

The priority will be established, first, of all, based on the type of action. With respect to experimental use permits, there will be a maximum processing time of 120 days, which is the statutory limitation set into the system. The priority will then escalate, the closer one gets to that deadline, so that things will not be handled as they have in the past on a first-in-first-out basis. Rather, the action will accelerate in priority with its age in the system so that we will tend to get more of these things done before the statutory deadline comes up.

The second thing that I would like to comment on are the guidelines for experimental use permits. The letter is correct. They have not been put out in final form yet and are being worked on. We are trying to build flexibility into those guidelines. The regulations themselves provide a degree of flexibility. The usual research program begins with green house research for effectiveness and then moves into small plot testing which does not require an experimental use permit. Third, it moves into the full-scale field experiment, so that there is a fairly good indication of the viability of the compound at that time.

However, we do try to take into account the amount of pesticide that is going to be used. That, frankly, is one of the things that complicates writing guidelines in this area—trying to provide that flexibility.

I do not have a deadline date with me but I can provide for the record our estimated date for publishing those guidelines.

Mr. FITHIAN. All right. I thank you.

Perhaps you will do me the favor of sending along a written response to my inquiry.

I do not, Mr. Chairman, at this time intend to clutter up the bill with an amendment on this; yet I would like to see this administratively addressed. I think it can be.

If you could send me along a written reply I will forgo an amendment.

Mr. JOHNSON. We would be pleased to send that along.

Mr. DE LA GARZA. Thank you very much, sir. We appreciate your patience and cooperation.

The subcommittee stands adjourned subject to the call of the Chair.
[Additional material submitted follows:]

NATIONAL COTTON COUNCIL OF AMERICA



EXECUTIVE BUILDING / 1030 FIFTEENTH STREET, N.W. / SUITE 700
WASHINGTON, D.C. 20005
TELEPHONE: (202) 833-2943

April 30, 1980

The Honorable E. de la Garza
Chairman
Subcommittee on Department Investigations,
Oversight and Research
House Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Cotton producers are becoming increasingly concerned over recent proposals by the Environmental Protection Agency apparently implementing several recommendations contained in a petition by Friends of the Earth. Because of the seriousness with which we view the direction EPA appears headed, we would like to share our concerns with the Committee as it considers legislation extending EPA's authority to regulate pesticides. Therefore, we respectfully request that the attached statement be included in the hearing record.

We appreciate this opportunity to present our views.

Sincerely,

Randall T. Jones
Washington Representative

RTJ/cc

April 8, 1980

Document Control Officer
Chemical Information Division (TS-793)
Environmental Protection Agency
Room 447, East Tower, Waterside Mall
401 M Street, S.W.
Washington, D. C. 20460

Dear Sirs:

Re: Petition Notice No. PR-80-1

We are writing you in response to the January 17, 1980, Federal Register notice requesting comments on the petition of the Friends of the Earth (FOE) for rulemaking and policy changes on aerial application of pesticides.

The National Cotton Council, headquartered in Memphis, Tennessee, is the central organization of the cotton industry, representing producers, ginners, cottonseed crushers, merchants, warehousemen, cooperatives, and manufacturers.

Attached are our comments and suggestions regarding this matter. We have submitted an identical statement to the Federal Aviation Administration.

We are gravely concerned about the impact of the FOE proposed rules on agriculture. Many of the items in FOE's proposal are not needed and/or not practical.

While we think the FOE proposal borders on the ridiculous and has caused loss of many hours and expense by numerous private and public persons and groups who are compelled to respond, we do appreciate the opportunity to submit our views.

Sincerely,

Earl W. Sears
Executive Vice President

EWS/bis

Attachment

(The January 17, 1980, Federal Register notice, pp. 3316-3325, is held in the subcommittee file.)

COMMENTS FROM
NATIONAL COTTON COUNCIL OF AMERICA
TO
FEDERAL AVIATION ADMINISTRATION
AND
U. S. ENVIRONMENTAL PROTECTION AGENCY
ON
PETITIONS OF THE FRIENDS OF THE EARTH FOR RULEMAKING AND
POLICY CHANGES REGARDING AERIAL APPLICATION OF PESTICIDES
FAA DOCKET NO. 19448; PETITION NOTICE NO. PR-80-1
(Federal Register Notice, January 17, 1980)

April 9, 1980

General Comments

Implementing the rules as proposed in the Friends of the Earth (FOE) petitions will have a severe adverse impact on cotton and all of agriculture in the United States. This in turn will adversely affect this country's economy. Farmers and pesticide applicators cannot abide by rules proposed by FOE and stay in business.

We are obviously opposed to careless and irresponsible application, handling, and use of pesticides, but feel that current FAA and EPA regulations are adequate to protect non-target organisms and areas. We support strict enforcement of present rules against careless, irresponsible applicators.

Comments on Specific Points

Language Conformance -- We agree that language of the FAA regulations should be in reasonable conformance with the nomenclature of existing pesticides.

Overlapping Regulatory Responsibilities -- There should be a minimum of overlap between EPA and FAA in regulating and enforcing aerial application of pesticides. Overlap can create confusion for applicators. It can also lead to poor or inadequate, and sometimes unjust, enforcement activities. We do not believe FAA regulations should deal with flight procedures for specific

crops, directing use of particular application techniques, nor prescribe the kinds of pesticides to be used. FAA regulations prohibiting the dispensing of pesticides for uses other than those for which they are registered are unnecessary since EPA regulations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provide adequate enforcement authority. If FAA continues to have such a provision in its regulations, that provision should be changed to indicate prohibition against dispensing pesticides for use other than that which they are registered by EPA under Sections 3 or 5 of FIFRA or by states under Section 24 of FIFRA.

Drift Control Agents -- We believe that the use of anti-drift agents should be encouraged, especially with the more toxic chemicals. However, we do not believe drift control agent technology has reached a level where it can be considered as a mandatory label requirement.

Prior Public Notice of Broadscale Spray Programs -- Reasonable prior notice of broadscale spray programs by federal, state, and local governments is desirable. However, it is totally impractical to require prior public notice for each application in a broadscale program. A case in point would be a local mosquito control spray program where it would not be practical to issue a public notice prior to each run an applicator makes.

Appropriate Role of FAA in Aerial Application of Pesticides -- FAA's regulatory responsibility should be directed solely toward safe agricultural aircraft operations. EPA's regulatory responsibilities adequately cover everything else.

Utility of More Explicit Application Practices and Use Restrictions on Pesticide Labeling -- Explicit federal labeling requirements on nozzle sizes and types, application flight schedules, etc., are not practical. Achieving adequate pest

control with minimum drift or adverse effects from aerially applied pesticides is dependent upon many factors that vary from one location to another. Local authorities are in best position to recommend application practices.

Communicating Information on IPM Through Labeling -- Labeling is not a practical or effective means of communicating information on or promoting integrated pest management. (While IPM is not new, it is still developing and much research remains to better define economic threshold populations of pests, beneficials, and many other aspects.) The state/federal cooperative extension service program is the most appropriate and effective means.

Advance Notice and Written Permission: Broadscale Spray Programs vs. Local Agricultural Applications -- It would be totally impractical to require advance notice for local agricultural applications. Likewise, it would be totally impractical to require written permission to spray from adjoining property owners for either broadscale spray programs or local agricultural applications. Timeliness in spray applications is very critical with regard to most pesticide uses. Farmers cannot afford delays that would be caused by a requirement for written permissions.

Injuries From Aerial Application of Pesticides vs. Passenger Plane Crashes -- FOE contends that many more people are injured each year due to aerial application of pesticides than due to passenger plane crashes. This may or may not be true. FOE should submit documented evidence to substantiate this. What about deaths from the two causes? FOE obviously is trying to create emotional fear about pesticide spraying.

Volume of Violations of Present Regulations -- FOE states there is evidence of widespread violation of present regulations against creating hazard to

persons or property. We offer two comments on this allegation. First, we disagree that such violations are widespread. Where violations do occur because of careless, irresponsible applicators, we support proper enforcement penalty measures under the present law. Our second point is that FOE, in its own statement here, raises doubt about the need for new regulations which it proposes in other parts of the petitions. Rather than new regulations, maybe what is needed is better enforcement of present regulations.

Impact of Insurance -- FOE states that relatively low spray damage insurance cost makes it financially attractive for one landowner to spray another landowner's property and implies that the landowner doing the spraying doesn't care whether he sprays his neighbor's property. This borders on being a malicious statement. We know of no farmer who is so unconcerned about his neighbors that he doesn't care if their property is also sprayed. In addition, pesticides are expensive and farmers are interested in getting the most effective pest control at the least cost. This means maximum deposition of the pesticide spray on the target crop.

Buffer Strips -- For spraying highly toxic pesticides, we recommend reasonable but adequate buffer strips around school grounds and other such public places when there are authorized activities at these sites. However, we think state and local authorities are best able to specify and enforce rules of this nature.

FOE's Proposed Point Penalty System -- FOE claims that this system is very simple. "When a pilot sprays an area for which written permission has not been arranged, he loses points on his license." FOE further equates simplicity of this system to that of the point system used in some states for driving (auto) violations. We don't think the two systems can be equated. The aerial spraying violations are much more of a judgmental nature than most driving violations.

Who determines whether an aerial spraying violation has been committed? On what basis? Is it the owner of the non-target property that allegedly is sprayed? We have been told of instances where people on adjacent property complained of illness after agricultural aircraft seeded crops, and even sprayed distilled water.

FOE suggests a point system encompassing 15 categories of violations with specific points ranging from 1 to 10 for each. It would be almost impossible to determine if some of these "violations" actually happened. How and who would determine damage to a biological control program or an integrated pest management program for a crop belonging to another person? Pest insects as well as beneficial insects are mobile and move from field to field and farm to farm. Populations of either or both on one farm can be affected by spraying on another farm even though the spray is confined to the targeted farm.

FOE Reference to Alsea, Oregon, Situation -- FOE refers to the Alsea, Oregon, situation as a health epidemic of miscarriages. The Alsea II report has been reviewed by Oregon State University scientists and many other scientists who have discounted this report.

Sensitive Crops -- FOE claims that sensitive crops cannot be grown in "vast" territories of the United States because of herbicide spray drift. This most certainly is not the case. We suggest that FOE identify these "vast" territories including the sensitive crops and herbicides.

Survey of FAA Files for Pilot License Revocations -- FOE suggests that FAA survey its files to determine how many times the Administration has removed pilot licenses for spraying a person without his permission, for severe damage to property not in the spray contract, and for killing a person or his animals

with aerial spray. We don't see the need but have no objection to such a survey as long as it covers only those cases or episodes where it is documented that one of these unintended results actually occurred.

Relationship of Present FAA Program to Non-Target Spraying -- FOE says it believes FAA's present program guarantees routine spray drift to people and properties not in the contracted spray area. This is a ridiculous and malicious accusation.

Size of Identification Numbers on Planes -- We have already stated that we support enforcement actions against careless, irresponsible aerial applicators. In this respect, we agree with FOE that identification numbers on applicator planes should be of sufficient size to make identification easy.

Amount of Aerially Applied Pesticides Landing on Someone Else's Property -- FOE says EPA estimates that, based upon actual field tests, 40 percent of pesticides delivered by airplane lands on someone else's property. We have checked with both EPA and FAA officials to obtain a specific reference and determine the accuracy of such an estimate. As best we can determine, the probable source was a study done by Midwest Research Institute (MRI) and RvR Consultants under contract for EPA's Office of Pesticide Programs. The results of this study were published as EPA-540/9-75-025, July 1975, entitled, "A Study of the Efficiency of the Use of Pesticides in Agriculture."

Information for the MRI/RvR study was obtained from a literature search, questionnaires, personal and telephone interviews, and correspondence. These two contracting groups did not conduct any drift experiments or monitor drift under actual aerial application operations. They estimated the percent drift over 1,000 feet from the target crop under specified conditions. Assuming

their estimates are reasonably correct, it cannot be construed from such estimates that 40 percent of the pesticides delivered by airplane lands on someone else's property.

Sec. 137.3, Definition of "Agricultural Aircraft Operation" -- We are at a loss as to why the dispensing of live insects is specifically excluded from the definition of "agricultural aircraft operation."

Sec. 137.39(a), Economic Poison Dispensing -- This should be revised by using the term "pesticide" in the place of "economic poison" and "U. S. Environmental Protection Agency" instead of "U. S. Department of Agriculture."

Sec. 137.39(a)(2), Economic Poison Dispensing -- Use the term "U. S. Environmental Protection Agency" in place of "U. S. Department of Agriculture."

Sec. 137.51, Operation Over Congested Areas: General -- FOE says "other methods such as integrated pest management are available to delineate where ground control would be desirable." By this statement, FOE shows it has no conception of what integrated pest management is.

Classification of All Aerially Applied Pesticides as Restricted -- FOE requests that all pesticides applied by airplane be classified as restricted pesticides for that application. We contend that such action by EPA would make a farce of the pesticide classification program. We further contend that, in developing the 1972 amendments to FIFRA, Congress had no intent for EPA to take such action.

FOR THE RECORD



NATIONAL FOREST PRODUCTS ASSOCIATION

1619 Massachusetts Avenue, N. W., Washington, D. C. 20036

Statement of the
National Forest Products Association
before the
Department Investigations, Oversight, and Research Subcommittee
of the
Committee on Agriculture
U.S. House of Representatives
Regarding H.R. 7018
April 29, 1980

Mr. Chairman and Members of the Subcommittee:

Thank you for this opportunity to present the views of the National Forest Products Association (NFPA) on H.R. 7018, a bill to extend the Federal Insecticide, Fungicide, and Rodenticide Act until September 30, 1981. NFPA is composed of thirty-one regional and wood products associations and fourteen corporate members representing more than 2,500 companies in the forest industry.

NFPA supports the Subcommittee's bill, H.R. 7018, to authorize FIFRA appropriations for one year. While supporting H.R. 7018, NFPA also urges this Subcommittee to exercise its oversight responsibilities to insure a reasonable and workable implementation of FIFRA; an implementation that provides safe pest control methods and effective control of pests.

The food, fiber, and forest production capacity of the United States is an essential asset to our nation's high standard of living and its role as a world power. The scientific and technological skills of this nation are also important assets for the development and use of safe, efficient pest control methods that help achieve the full productivity potential of agriculture and forestry.

Chemical pesticides have provided an effective pest control tool in forestry during the past 40 years. This tool is particularly important for the short-term control of widespread forest insect attacks. Chemical pesticides are now one of the essential tools along with mechanical, biological, cultural, and prescribed fire methods of pest control to protect the major investments of growing forest crops.

The forest industry, concerned about the health and safety of its employees and its neighbors, is interested in using pesticides that are considered safe. We support the federal pesticide regulation approach of FIFRA and look to it for a complete and fair evaluation of the risks and benefits of pesticide use.

We urge the members of this Subcommittee, working in conjunction with their colleagues on the Appropriations Committee, to insure that EPA and USDA provide national leadership in pesticide regulation and pest control. This leadership is needed to merit the respect and confidence of state legislatures and pesticide regulators, chemical manufacturers, pesticide users, scientists, and the public.

Without strong, impartial national leadership, pesticide use decisions could become a hopeless chaos of state/county pesticide registration and use regulations based on fear and emotion rather than scientific fact and reason.

The following issues should be included in oversight hearings of this Subcommittee:

1. A national pesticide regulation program that serves both human health and pest control needs.
2. Cooperative programs between federal and state agencies, registrants, users, and other interested groups for obtaining needed information on the health risk and benefits of pest control methods.
3. Utilization of impartial scientists for assessment of pesticide health risk questions and establishment of dosage limits.
4. New approaches for impartial assessment of the human hazard, risk, and benefits of pest control methods in relation to other societal risks.
5. An EPA/USDA program to educate the public about the benefits and risks of pesticide use.
6. Procedures for determining minor use status for forest pesticides used in forest tree nurseries, greenhouses, seed orchards, and other low-volume uses.
7. Imposition of pesticide use restrictions (such as buffer strips) only after a factual determination by qualified experts that they are needed.

We appreciate this opportunity to express our views to the Subcommittee and stand ready to provide additional information on the issues of concern to us.

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